

**Evaluation of Tuberculosis Program Services  
For Burmese Refugees in Thailand  
Resettling to the United States**

June 2007

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# **Evaluation of Tuberculosis Program Services for Burmese Refugees in Thailand Resettling to the United States Executive Summary**

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In 2005, an outbreak of multidrug-resistant tuberculosis (MDR TB) was detected among a group of 15,000 displaced Laotian Hmongs living in Thailand at Wat Tham Kraboc, who were being screened by the International Organization for Migration (IOM) prior to resettlement in the United States with refugee status. MDR TB was found in extremely high incidence in that population, with cases being detected both at the camp during the screening process and in the U.S. after screening and resettlement. The latter finding led to an emergency assessment and response on the part of the Division of Global Migration and Quarantine (DGMQ) and the Division of Tuberculosis Elimination (DTBE), Centers for Disease Control and Prevention (CDC) in cooperation with the IOM. As a part of that response, a set of interim Technical Instructions that included, for the first time, mycobacterial culture and drug susceptibility testing were instituted specifically for the Wat Tham Kraboc screening program.

In February 2006, the Advisory Council for the Elimination of Tuberculosis (ACET) recommended that the interim Technical Instructions drafted for the Wat Tham Kraboc screening should be evaluated to determine their impact on the effectiveness of the overseas screening of that and similar populations that have been granted refugee status by the U.S. Government (hereinafter in this report termed “refugees”). Because of timing issues, the assessment was conducted in April and May 2007 at the start of a large-scale screening program being established by IOM for Burmese refugees living in the Mae La Displaced Persons Camp on the Thai-Burmese border. The two primary objectives of the program evaluation were to provide recommendations to the IOM for the screening, diagnosis, and treatment of refugees resettling to the U.S. from Thailand, and to provide recommendations to CDC’s DGMQ and DTBE for improving the effectiveness and practicality of the 2007 new tuberculosis Technical Instructions.

The Evaluation Team organized itself through a series of conference calls in early 2007 and convened in Bangkok on April 28, 2007. Team members conducted a 4-day visit to inspect IOM screening activities at the Mae La Camp and the Pha Wo Hospital in the nearby city of Mae Sot, Thailand. Team members, working together and in small groups, observed all aspects of the screening process, conducted structured patient and key informant interviews, reviewed patient records and chest radiographs, and discussed in detail with the IOM Regional Medical Officer, Laboratory Manager, and Panel Physicians the recommendations endorsed by the American Thoracic Society (ATS), the CDC, and the Infectious Diseases Society of America (IDSA) for diagnosis and treatment of tuberculosis. These recommendations constitute the scientific basis of the new Technical Instructions, as well as the general approach to TB control in U.S. states and counties.

A number of notable findings were made by the Evaluation Team. The Team was highly impressed by the IOM refugee screening program. IOM's long experience in conducting TB screening for the U.S. government among refugees shows clearly in its organization and patient-centered implementation of this complex screening program with requirements to process 15,000 refugees from Mae La Camp between April and the end of September 2007. At the same time, a number of challenges that IOM faces, such as the need for clinical consultation on difficult cases, ongoing training of medical, radiological, and laboratory staff members, and high contamination rates in the Bactec Mycobacterium Growth Indicator Tube (MGIT) culture system, were explored in depth. Likewise, the team discovered that IOM staff members are uncertain about some aspects of the 2007 new Technical Instructions, such as the nature of radiographic abnormalities that should trigger sputum smear and culture examination, the diagnosis and management of smear- and culture-negative and extrapulmonary TB, and the work-up of contacts to infectious TB cases.

As a matter of great interest to the TB control professionals in the U.S., the Evaluation Team's review of data from several sources suggested that the burden of TB among Burmese refugees living in Thailand prior to resettlement is high, likely to be comparable to that among Hmong refugees. However, preliminary data on drug susceptibility testing suggest that there is likely to be a far lower proportion of MDR TB in the Burmese refugee population than was found in the Hmong refugee population.

The Evaluation Team has prepared a set of recommendations for IOM designed to help the organization improve its already very good refugee screening program. Recommendations were made to address the MGIT contamination rate, to ensure standardization of its TST program, to enhance opportunities for clinical training in diagnosis and treatment of TB according to ATS/CDC/IDSA guidelines for panel physicians, and for interpretation of the interim technical guidelines with respect to criteria for sputum collection and suggestions for clinical management decisions on culture-negative TB, extrapulmonary TB, and contacts to infectious TB cases. The team also held an exit interview and discussed these recommendations in depth with the IOM Regional Medical Officer.

The Evaluation Team also developed a set of recommendations for ways that DGMQ and DTBE can improve overseas refugee screening. A set of indicators was drafted to facilitate monitoring and evaluation of this and other programs that are implementing culture and drug susceptibility tests (DST) according to the 2007 new Technical Instructions. The Divisions were called upon to specify minimum levels of required training for panel radiologists and panel physicians and to provide opportunities for such training to be obtained. The team recommended the establishment of a network of knowledgeable and interested clinical consultants in the U.S. that could assist panel physicians with difficult screening and treatment decisions, perhaps based on e-mail transfer of clinical and radiographic data. The Evaluation Team concluded that DGMQ, with regulatory authority and DTBE, the reservoir of technical expertise on TB, must continue to work together seamlessly in order for refugee screening programs to succeed.

Finally, the Evaluation Team presented a number of recommendations designed to clarify and amend the interim Technical Instructions. The instructions on contact evaluation, diagnosis, and follow-up are ambiguous and should be revised, with incorporation of TST into the evaluation. The recommendation for not treating extrapulmonary TB should be reworded. For this program at least, the routine screening of B1 refugees at three weeks prior to departure should be retained until its value can be adequately assessed.

In its overall assessment of the 2007 new Technical Instructions, The team concluded that the data from the Wat Tham Kraboc and especially from the IOM screening program at the Tham Hin Camp, which immediately preceded that at the Mae La camp, suggest the immense value that mycobacterial culture and DST can add to a refugee screening program. Although the challenges of establishing the laboratory capacity for culture and DST are not trivial, the Evaluation Team believes that this program allows an intriguing glimpse of the future of TB control among refugees and immigrants and should be thoroughly evaluated and if feasible, aggressively expanded. DGMQ and DTBE are to be commended for adding this interim requirement, ending years of debate about culture and DST in screening programs, and IOM is to be especially commended for demonstrating its added value to refugee screening.

## Background

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Each year, approximately 400,000 immigrants and 50,000 refugees enter the United States from overseas locations.<sup>1</sup> These applicants for U.S. immigration are required to undergo medical screening for diseases of public health significance, referred to as inadmissible conditions, which include infectious tuberculosis. The Division of Global Migration and Quarantine (DGMQ) at the Centers for Disease Control and Prevention (CDC) has regulatory authority to stipulate the requirements of the overseas medical examination in Technical Instructions specific to each inadmissible condition (42 CFR Part 34).<sup>2</sup>

Worldwide, the physicians who perform the required medical screening are called panel physicians. Panel physicians are offered agreements by the Department of State to serve in this capacity. Immigrants pay for the cost of their required screening, while the Bureau of Populations, Refugees, and Migration (BPRM), Department of State, funds the screening of refugees.

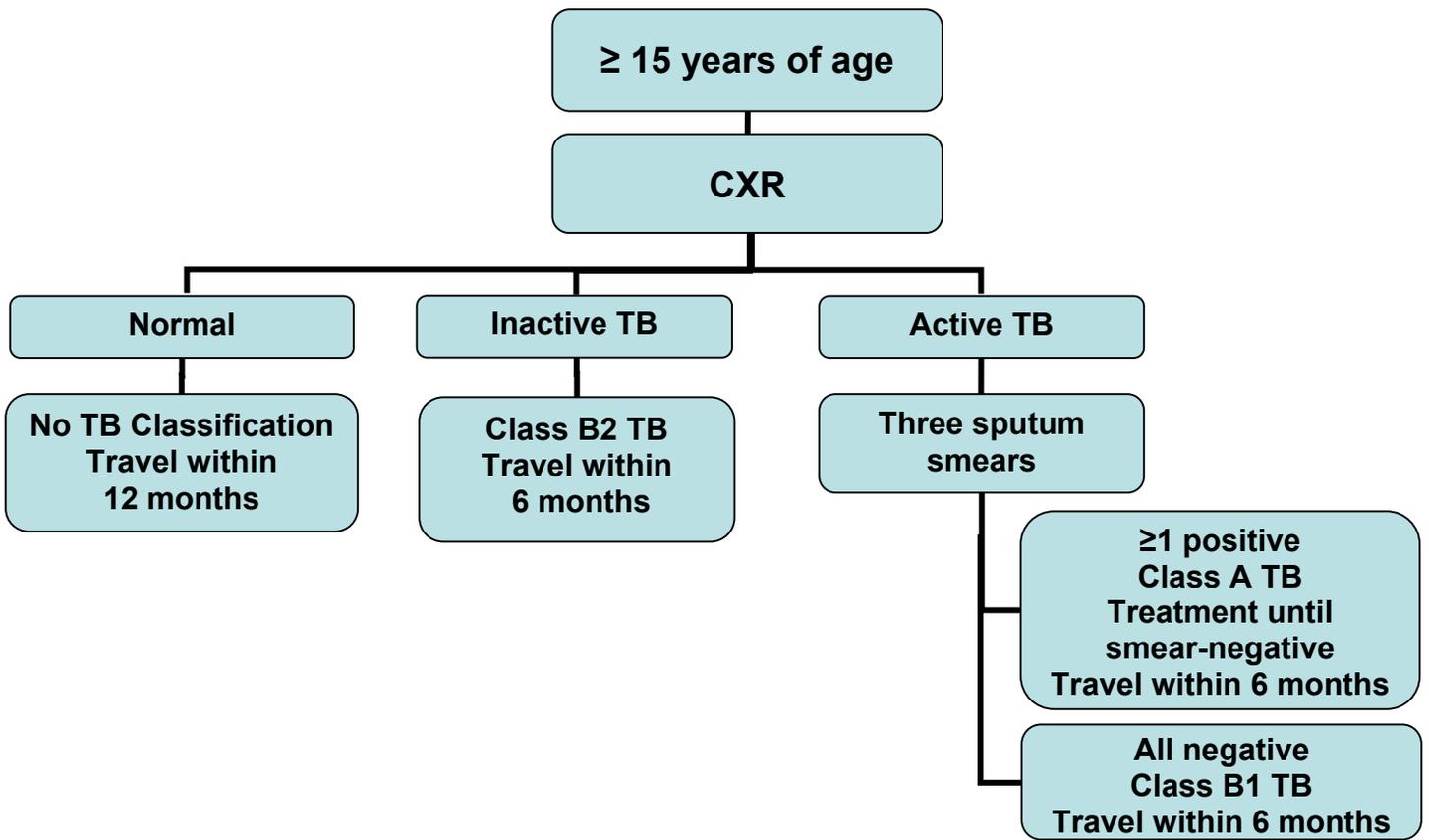
BPRM is the State Department bureau responsible for refugee resettlements. To support this effort, BPRM has contracted the International Organization for Migration (IOM) to perform the medical screening for approximately 80% of the refugees. IOM is an organization that works in many countries on issues related to migrating populations.

DGMQ provides technical oversight of the medical screening and designates teams who perform on-site visits using standardized evaluation tools. For TB, DGMQ also identifies or helps develop TB laboratory and directly observed therapy (DOT) facilities.

The CDC Division of Tuberculosis Elimination (DTBE) provides subject-matter expertise to DGMQ in overseeing the tuberculosis screening portion of the required medical examination. This oversight has included consultation with and advice to DGMQ on various aspects of the screening algorithm used to detect tuberculosis and manage patients who are diagnosed with tuberculosis during the screening process. DTBE has, in turn, consulted with various groups for technical review of this work, including the federal Advisory Council for the Elimination of Tuberculosis (ACET) and the National Tuberculosis Controllers Association (NTCA).

The Technical Instructions for Tuberculosis (TB TI) were issued in 1991 (Figure 1). These instructions require chest radiograph (CXR) for applicants  $\geq 15$  years of age. Applicants with a CXR suggestive of tuberculosis must provide three sputum specimens, which undergo microscopy for acid-fast bacilli (AFB). Applicants with  $\geq 1$  positive sputum smears are required to postpone travel to the United States and to undergo treatment for tuberculosis disease until sputum smears are negative. Medical clearance is valid for 12 months for applicants with a negative CXR and 6 months for applicants with a CXR suggestive of tuberculosis but with sputum smears negative for AFB.<sup>2</sup>

**Figure 1.**  
**1991 Tuberculosis Technical Instructions**



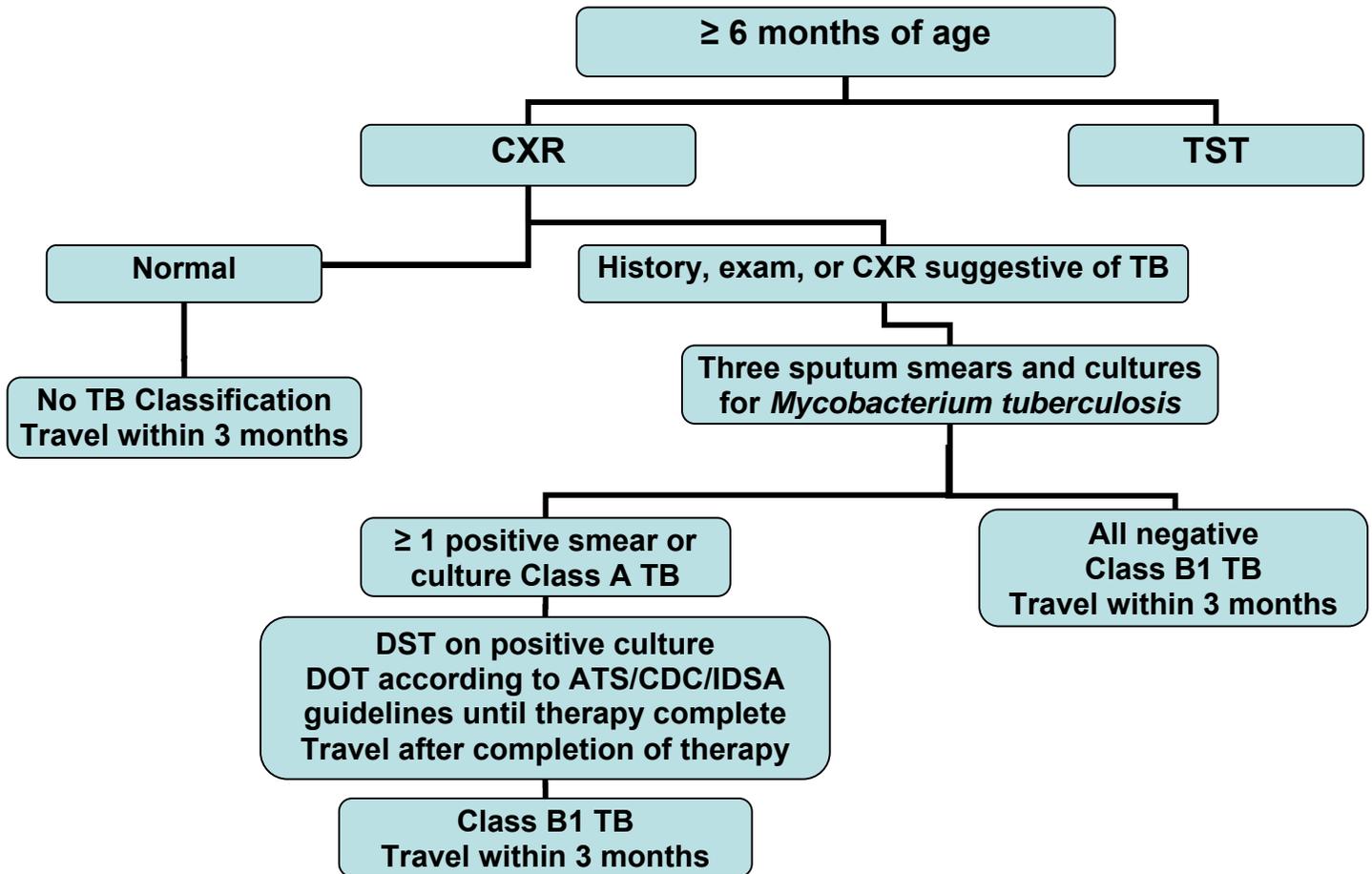
### Hmong Resettlement

In December 2003, the U.S. Department of State approved resettlement of over 15,000 Laotian Hmong refugees to the United States. Medical screening started in February 2004, and movement to the U.S. began in June that same year.

During 2004, after interim enhancements to the 1991 Technical Instructions specific for Hmong refugees, four cases of multidrug-resistant tuberculosis (MDR TB) were detected among the refugees in Thailand. This coincided with reports of tuberculosis disease among those who had arrived in the United States.<sup>3</sup>

Based in part on these findings and the results of the ensuing epidemiologic investigation, the algorithm for the Hmong refugees was revised in February 2005, with minor changes in June 2005, such that the final algorithm included CXR and tuberculin skin test (TST) for all refugees  $\geq 6$  months of age. In addition, the algorithm specifies that screening must be performed within 3 months of travel (Figure 2).<sup>4</sup> This protocol is known as the final Hmong algorithm.

**Figure 2.**  
**Algorithm Implemented for the Hmong Refugee Resettlement,**  
**“Final Hmong Algorithm”**



As of June 2007, , a total of 15,361 Hmong refugees had been resettled from Thailand to the United States (Table 1). Of these, 54 have been diagnosed in the United States with TB disease. The rate of TB (508 per 100,000) in refugees who were resettled before February 2005 was much higher than the rate of TB (102 per 100,000) among the refugees who were resettled after February 1, 2005, when the final Hmong algorithm was instituted.

**Table 1.**  
**Tuberculosis Cases Diagnosed in the United States among Hmong Refugees, updated as of June 2007**

	<b>Resettled Before 2/1/05</b>	<b>Resettled After 2/1/05</b>
<b>Hmong refugees resettled in the United States</b>	9,455	5,906
<b>Hmong refugees diagnosed in the United States with TB disease (rate/100,000)</b>	48 (508)	6 (102)
<b>Culture positive for <i>Mycobacterium tuberculosis</i></b>	14	4
<b>Multidrug-resistant TB (%)</b>	7 (50%)	2 (50%)

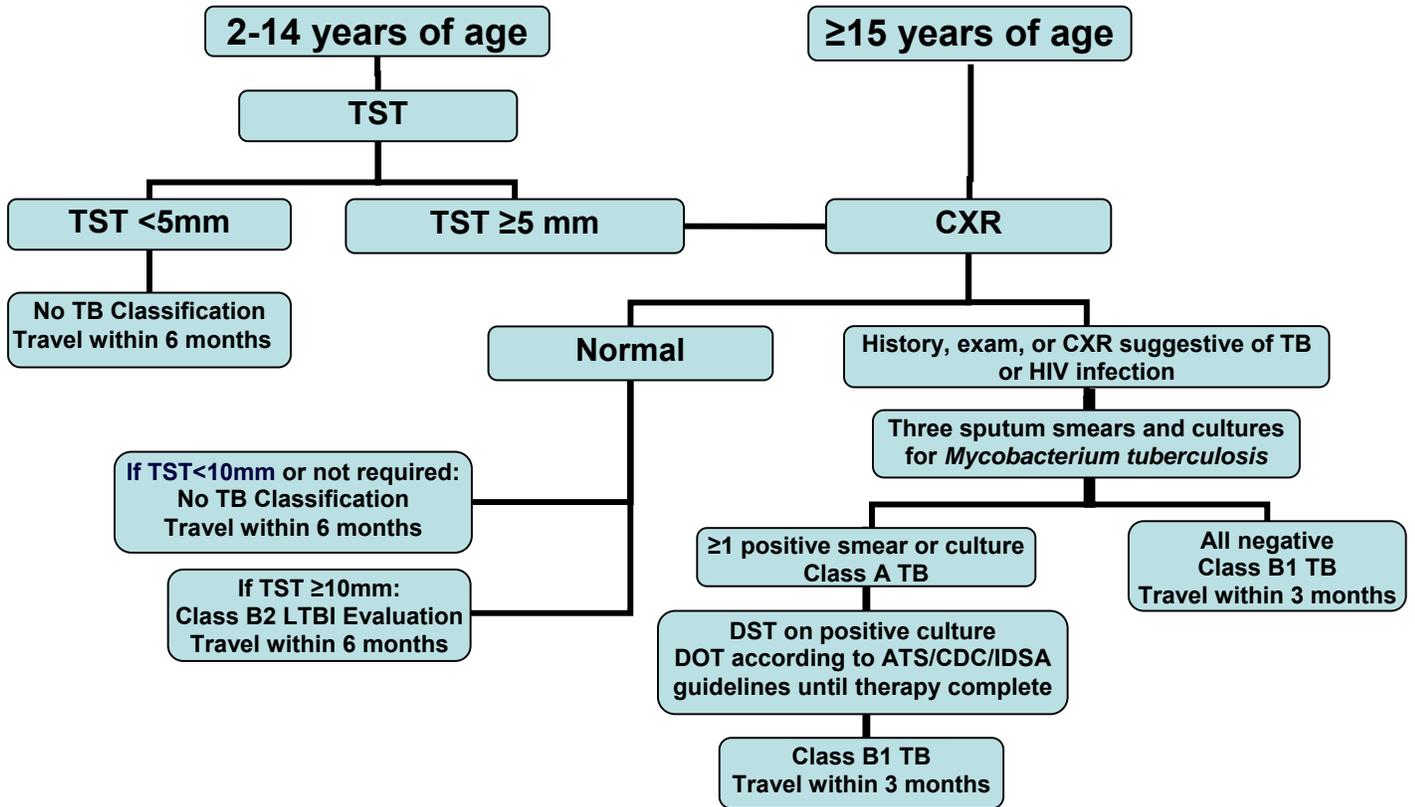
### **2007 New Technical Instructions for Tuberculosis Screening and Treatment**

The experience with the Hmong refugee resettlement underscored the importance of modernizing the 1991 TB Technical Instructions. In particular, the Hmong resettlement and a study among immigrants in Vietnam demonstrate the failure of the 1991 TB Technical Instructions to detect smear-negative, culture-positive cases of tuberculosis disease.<sup>5</sup> Additional studies have demonstrated the challenges to prevent importation of TB disease.<sup>6-8</sup> In addition, the U.S. tuberculosis community has recommended updating the TB Technical Instructions, with consideration given toward incorporating mycobacterial cultures and tuberculin skin testing (TST) into the algorithm and developing classifications for applicants suspected of having latent *Mycobacterium tuberculosis* infection (LTBI).<sup>9-12</sup> The emergence of extensively drug-resistant tuberculosis (XDR-TB)<sup>13</sup> further reinforces the importance of an overseas screening system for U.S. immigration applicants that can detect and adequately treat TB disease overseas.

To better detect and treat tuberculosis disease overseas and improve the risk stratification of applicants, the TB Technical Instructions were modernized (Figure 3). The new Technical Instructions continued to specify that those 15 years of age and older would receive CXRs. Applicants <15 years of age living in countries with a World Health

Organization (WHO)-estimated tuberculosis incidence rate of  $\geq 20$  cases per 100,000 population should have a TST. If the TST is  $\geq 5$  mm, a CXR should be performed. Sputum smears and mycobacterial cultures are required for applicants with CXR suggestive of tuberculosis disease, and DST is required on positive isolates. Applicants with smear- or culture-positive tuberculosis must receive therapy delivered as directly observed therapy (DOT) according to the American Thoracic Society, CDC, and Infectious Diseases Society of America TB treatment guidelines.<sup>14</sup>

**Figure 3.**  
**2007 New Technical Instructions for Tuberculosis Screening and Treatment, for**  
**Applicants in Countries with WHO-estimated Tuberculosis Incidence Rate of  $\geq 20$**   
**Cases Per 100,000 Population**



Initially, the new TB TI lowered the aged at which CXR was required to 6 months of age, and TST was required for applicants 6 months through 5 years of age. These new TB TI were issued to the Department of State on January 16, 2007. However, following a legal review by the Department of Health and Human Services Office of General Council, the TB TI for applicants <15 years of age were changed to what is described above. These changes were issued to the Department of State on April 25, 2007, for implementation. The TB TI with these most recent modifications are referred to as the new TB TI in this report.

Use of the new TB TI is expected to increase detection of tuberculosis cases overseas, prevent importation of tuberculosis (including drug-resistant tuberculosis) into the United States, and contribute to global tuberculosis control efforts.

### **ACET Evaluation**

After the final Hmong algorithm was implemented, the Advisory Council for the Elimination of Tuberculosis (ACET) recommended during its tri-annual meeting on February 16, 2006, that a team review and evaluate the Hmong tuberculosis control program. The purpose was to evaluate the effectiveness of the changes, both with respect to the Hmong resettlement and to inform the TB TI revisions. At the time of the request, over 95% of Hmong refugees had resettled. It was ultimately decided that a review should occur with a future refugee resettlement from Thailand, where BPRM is in the processing of resettling approximately 140,000 Burmese refugees, during which the FHmA or the new TB TI would be used.

During the summer of 2006, Burmese refugees from the Tham Hin camp in Ratchiburi Province were offered resettlement and approximately 4,700 have been resettled so far. Another 600-800 persons are expected to be moved from the camp by the end of FY2007. The Burmese refugees at Tham Hin were screened according to the final Hmong algorithm. Unfortunately, the ACET-requested evaluation could not be arranged to occur during the resettlement from Tham Hin.

The next Burmese population identified for resettlement is located at the Mae La Displaced Persons Camp near Mae Sot. The Mae La Camp is the largest refugee camp in Thailand along the border with Burma. There are approximately 45,000 refugees in the camp, nearly all of whom are Karen. Many have been living there since the camp opened in 1984. BPRM has offered resettlement to these refugees and is working to resettle 15,000 refugees before September 30, 2007. Screening for these refugees began April 9, 2007, according to the new TB TI; screening with the appended TB TI for applicants <15 years of age began April 30, 2007.

In working with ACET, the National Tuberculosis Controllers Association (NTCA), and IOM, DTBE and DGMQ were able to arrange for a team to travel to Thailand in late April and early May 2007 to evaluate the refugee resettlement program and the 2007 new TB Technical Instructions.

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## **Purpose and Objectives**

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The purpose of the Program Evaluation Team was to conduct a program evaluation and provide an objective, in-depth, sensitive assessment of IOM's operation within Thailand in relation to the application of the new TB Technical Instructions. The Program Evaluation Team included members from CDC (DTBE and DGMQ) and partners (National Tuberculosis Controllers Association and Advisory Council for the Elimination of TB). Team members interviewed key IOM staff, visited Pha Wo Hospital to review the medical screening facility, radiology facility, and the laboratories at Pha Wo General Hospital and Wat Tham Krabok to observe TB services being provided. Team members traveled to Mae La Camp to observe early morning sputum collection, the DOT program, and education sessions for the refugees. The team was also charged with providing a written report, prior to departing Thailand, outlining the findings, observations, recommendations, and an overall assessment of the program.

### **Specific Project Objectives:**

1. Provide recommendations to the International Organization for Migration for the screening, diagnosis, and treatment of TB in refugees re-settling to the U.S. from Thailand.
2. Provide recommendations to CDC's Division of Global Migration and Quarantine and Division of Tuberculosis Elimination for improving the effectiveness and practicality of the new Tuberculosis Technical Instructions.

## **General Description Mae La Camp**

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Mae La Camp is located in Tak Province, Thailand, approximately 8 kilometers from the Thai-Burmese border and 550 kilometers from Bangkok. The camp is 600 acres in size. This site was originally established in 1984 with a population of 1,100. In 1995, Mae La was designated as a consolidation camp for the smaller camps throughout the area and currently contains about 45,000 refugees, the largest number of displaced Burmese in Thailand, representing almost 1/3 of the total in-camp population on the Thai-Burmese border. About half of the population is under 18 years of age.

Primary health care in Mae La camp is provided by Aide Medicale Internationale (AMI). This is a humanitarian French association created in 1979. AMI provides its services through two outpatient department clinics (OPDs) with more than 200 consults daily, and one inpatient unit of 150 beds which includes a basic laboratory with AFB smear

capacity, but without an x-ray unit. AMI is also responsible for the provision of clean water and sanitation facilities for the refugees.

TB case finding is passive. Symptomatic patients are screened with smear microscopy by using direct smears. Three specimens are taken on 3 successive days. If AFB are detected, the patient is then transferred to Medecins sans Frontieres (MSF) for follow up.

Since 1997, MSF has provided the tuberculosis care for Mae La Camp. MSF has developed a “TB Village” in the camp in order to isolate potentially infectious TB patients from the general camp population and to facilitate DOT. The TB Village is located at the extreme end of the camp, up a steep hill. There are 3 sections in the camp: smear positive, smear negative, and MDR TB. The current population of the TB Village is about 220 persons, of whom 162 are TB patients and the rest are family members providing needed supportive care for the patients. MDR TB patients expect to remain in the TB Village for 2 years. Family members of MDR TB patients are requested to sleep in separate quarters from the patient.

The International Organization for Migration (IOM) is in charge of the transportation, logistical management, cultural orientation, and medical screening and clearance of refugees in Thailand who are to undergo resettlement to the US. If in the process of screening (screening policies to be described below), TB is detected, IOM has contracted to collaborate with MSF and will move refugees with pulmonary TB to the TB Village. These patients will, however, remain under the care of IOM physicians and DOT nurses. The maintenance of the logistics of the village will be through MSF.

Medical screening of US-bound refugees from Mae La Camp by IOM began on April 9, 2007 IOM is following the new Technical Instructions for Tuberculosis Screening and Treatment. The IOM screening process begins with TST placement and reading for refugees from age 2 through age 14. All persons then undergo a medical exam and, for those 15 and older, those with a TST of 5 mm or more, and those under 2 with clinical signs or symptoms of TB, a chest x-ray (with lateral if less than 10 years of age). Refugees with any findings of suggestive of pulmonary TB (including for this purpose pleural or laryngeal) will then have three morning sputum specimens collected for AFB smear and culture. Refugees with HIV infection will also have three sputum specimens collected even if the chest radiograph is normal. Refugees identified for sputum collection are shown a video on the Monday following their medical exam teaching them how to produce a sputum specimen. They are then told to come at 6:30 am on Tuesday, Wednesday, and Thursday for sputum collection. Collection is done by trained laboratory personnel under direct observation.

Any person found to have smear- or culture-positive TB is required to complete treatment for TB by ATS/CDC treatment guidelines under strict DOT management before being allowed to travel to the US. This treatment will be in the TB Village for the first 2 months under IOM nurse and physician care. After 2 months the patients with TB will be offered the choice of staying in the TB Village, or returning to the general camp and continuing DOT at the IOM treatment site in camp.

Refugees whose smears and cultures are negative for AFB or who have only extrapulmonary TB will generally not have treatment begun overseas, unless it would be detrimental to the health of the refugee to wait until after immigration to initiate treatment.

IOM utilizes a MiMOSA database (Migrant Management & Operational Systems Application). Patients are identified by their Alien ID number, and a photograph of each refugee is digitalized and printed on his/her ID card to ensure against fraud. This system allows lists of patients requiring TST or sputum collection to be easily generated as well as labels and bar codes for clinical and laboratory specimens. The database allows staff to generate aggregate information on numbers of refugees processed, sputum specimens ordered, TST results, results of sputum smear and culture testing, and treatment outcomes.

## Methods

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### Schedule and Description of Activities by Topic

During the first week of the evaluation, the team traveled from Bangkok to the city of Mae Sot, in the Thai province of Tak, to visit the Mae La Displaced Persons Camp to participate in discussions about the refugee medical screening program and to tour Pha Wo hospital, where IOM conducts refugee physical examinations, obtains chest radiographs, and processes specimens at their laboratory. During the second week, the team met with IOM staff in Bangkok to gain additional information about the refugee screening process. In addition, some members of the team traveled to Wat Tham Kraboc to review the management of a small number of Hmong refugees being treated for tuberculosis. The team's schedule is outlined below.

### Team Schedule

Date/Time	Event
<b>May 1</b>	<b>Mae La Displaced Persons Camp</b>
	Review of camp activities
6:30 am	1. Sputum collection observation
7:15 am	2. DOTS program visit
8:00 am	3. AMI medical facility tour
9:00 am	4. MSF TB Village tour
	<b>Mae Tao Clinic</b>
2:00 pm	Tour of private clinic for persons who travel from Burma to Mae Sot for medical care

Date/Time	Event
<p><b>May 2</b> 9:00 am</p> <p>10:00 am 11:00 am</p> <p>11:30 am 1:00 pm</p> <p>2:00 pm 4:00 pm</p>	<p><b>Central Mae Sot Hill Hotel, Mae Sot</b> Roundtable discussion of refugee screening program with team members, IOM staff, and representatives from MSF and AMI. Presentations at Central Mae Sot Hills Hotel</p> <ol style="list-style-type: none"> <li>1. Dr. Jay Varma, TUC/DTBE – Thailand TB Surveillance Network</li> <li>2. Dr. Andres Romero, MSF – TB Village – A novel approach to TB treatment in a refugee camp setting</li> <li>3. Dr. Raz Wali, IOM – Refugee medical screening</li> <li>4. Warren Jones, IOM – TB screening and diagnosis for refugees</li> </ol> <p><b>Pha Wo Hospital</b> Presentation of IOM operations at Pha Wo hospital</p> <ol style="list-style-type: none"> <li>1. IOM Laboratory tour</li> <li>2. Radiography review</li> </ol>
<p><b>May 3</b> 10:00 am 11:00 am 12:00 pm</p> <p>9:00 am 9:00 am 10:30 am 11:30 am</p>	<p><b>Mae La Displaced Persons Camp</b></p> <ol style="list-style-type: none"> <li>1. DOT observation, DOT worker interview, patient interviews, refugee patient education sessions, TB/HIV, life skills, and cultural orientation</li> <li>2. AMI facility tour and interview of AMI Medical Director</li> <li>3. Observation of transfer of patient care from central IOM facility to TB Village</li> </ol> <p><b>Pha Wo Hospital</b> Concurrent review of procedures</p> <ol style="list-style-type: none"> <li>1. Laboratory procedures review</li> <li>2. Pharmacy procedures review</li> </ol> <p>Pediatric case review with IOM physicians IOM physician interviews</p>
<p><b>May 4</b> 8:30 am</p> <p>11:30 am</p>	<p><b>Pha Wo Hospital</b> Roundtable discussion with IOM staff of proposed recommendations</p> <p><b>In transit to Bangkok</b> Team member discussion of recommendations</p>
<p><b>May 7</b> 12:00 pm 2:00 pm</p>	<p><b>Marriott Hotel, Bangkok</b> Meeting with IOM staff to review findings</p> <ol style="list-style-type: none"> <li>1. Meeting with IOM Regional Medical Officer and IOM Resettlement Health Project Coordinator</li> <li>2. IOM director interview</li> </ol>
<p><b>May 8</b> 7:30 am</p>	<p><b>Wat Tham Kraboc</b> Visit to Wat Tham Kraboc and review cases with Dr. Melissa Varma</p>

### Case Definition

A TB case was defined by clinical diagnosis (chest radiograph consistent with TB, clinical presentation consistent with TB, and clinical or radiographic improvement on TB treatment regimen) or bacteriological confirmation by positive sputum smear for acid fast bacilli (AFB) and/or positive culture for *M. tuberculosis* species complex.

## **Methods Used for Review of Tham Hin Data**

### **TST, Smear and Culture Results**

Team members reviewed surveillance, treatment, and outcome data from previous TB screening performed by IOM at the Tham Hin Refugee Camp. Team members then compared this data with corresponding data from Wat Tham Kraboc collected both before the final Hmong screening algorithm was put in place and afterwards to identify similarities and differences.

### **Pediatric Case Review**

Team members reviewed the summaries of the 88 pediatric cases diagnosed at Tham Hin camp with IOM panel physicians and held discussions with these physicians regarding the medical management of six of these cases.

### **Chart Review**

Team members created a case patient record abstraction tool to collect data relevant to the new Technical Instructions on TB cases treated overseas by IOM. Using this abstraction tool, team members collected data on 20 active TB cases from Tham Hin camp selected at random. Team members then analyzed the data to evaluate the medical management and adherence to the new Technical Instructions of IOM physicians during this time period.

## **Methods Used for Evaluation of TB Screening at Mae La Camp**

### **TST Program**

Team members discussed the process of TST placement and reading with nurses involved with this program and interviewed one nurse with regard to TST training. Team members confirmed what PPD reagent was used for TST placement and researched the evidence that this solution was equivalent to PPD-S, as is stipulated in the TIs. Team members reviewed the TST reaction rates collected from refugees undergoing screening at Tham Hin camp and very preliminary data on TST reaction rates at Mae La camp.

### **Panel Physician**

Team members created a panel physician interview tool and interviewed three panel physicians with regard to refugee screening practices. Team members met with panel physicians, both individually and in group settings, to discuss cases, abnormal radiographs, the overall screening program, and challenges faced by panel screening and treatment physicians.

### **Radiology**

Team members created a radiology abstraction tool to collect information on the quality of radiographs and their interpretation. Three team members, who were blinded to the original IOM radiologic interpretations, used the abstraction tool to independently reviewed 15 chest radiographs. The overall radiograph technique used was rated as poor, intermediate, or good. The findings for each radiograph were classified as showing one of

the following: no abnormality suggestive of current TB disease, which included isolated findings of calcified granulomas, calcified hilar adenopathy, or pleural thickening; unilateral but not extensive findings suggestive of TB; bilateral but not extensive findings; extensive bilateral findings; and evidence of cavitation. The results were analyzed and compiled by one reviewer.

### **Sputum Collection**

Team members observed the sputum collection process for several individuals at the camp and discussed the process by which refugees are identified and brought in for sputum collection, including the teaching that occurred before sputum collection was conducted. Team members observed the specifics of labeling specimens and assessed the process from sputum collection to transport of the specimen to the laboratory.

### **Case Detection (AMI Evaluation)**

Team members toured the AMI facilities at Mae La camp and interviewed the AMI director with regard to TB screening, treatment, and management practices. Team members observed the processing of specimens at the AMI TB lab.

### **Data Management**

Team members discussed the collection, electronic entry, and periodic reporting of data obtained during the health screening process.

## **Methods Used to Evaluate Medical Management of TB Cases at Mae La Displaced Persons Camp**

### **Isolation Facility**

Team members visited the TB Village, which is the isolation facility for TB cases in Mae La camp. Team members discussed with IOM and MSF physicians the care and management of active TB cases in the village, in addition to referral strategy, transport, infection control practices, and other aspects of patient management.

### **DOT Program**

Team members created a DOT observation tool and a DOT worker interview tool. Team members reviewed IOM DOT policies and compared these policies with the Technical Instructions. Team members visited the DOT program facility, observed three active TB cases receiving DOT by two DOT nurses, and observed how future appointments for DOT were made. Team members used the DOT worker interview tool to interview one of the DOT nurses.

### **Family Contact Evaluation**

Team members discussed the management of family contacts of active pulmonary TB patients with the IOM director, IOM physicians, and other IOM staff. Team members reviewed the management of particular family contacts with the physicians.

### **Analysis of Early Health Screening Data from Mae La Camp**

Team members reviewed the TB surveillance data generated from TB screening of refugees from the beginning of health screening in early April 9, 2007, up to and including refugees screened on April 27, 2007, to determine number of persons screened, TST positivity rates, and number and prevalence of AFB smear-positive patients.

### **Active TB Case Review at Mae La Camp**

Team members created a TB case abstraction and interview tool to collect information on the first three TB cases diagnosed at Mae La camp. Team members performed chart reviews, reviewed case chest radiographs with IOM physicians, and performed patient interviews with each of the three TB patients to assess their knowledge of TB, experience with DOT, and possible concerns about their diagnosis and treatment.

### **Laboratory Evaluation**

Team members observed the process of sputum collection at Mae La camp and observed the smear microscopy facility at AMI. Team members visited the Pha Wo laboratory with the laboratory director and observed specimen transport and processing. Team members observed smear microscopy and AFB culture methods (MGIT and LJ). Team members held discussions with the laboratory director and reviewed the laboratory data from both specimens screened from Mae La and Tham Hin camps, including laboratory culture contamination rates in liquid and solid media.

### **Evaluation of Training and Education Program**

Team members observed the TB/HIV education session and one session of the cultural orientation class for refugees. Team members also reviewed educational materials being used. In interviews with patients, team members assessed TB knowledge. For staff training, team members asked IOM staff about the formal training received upon starting employment with IOM.

### **Evaluation of Pharmacy Services**

Team members visited the IOM pharmacy at Pha Wo Hospital and reviewed medication dispensing practices. The team members talked with nursing staff with regard to medication administration procedures for TB patients. Team members reviewed evidence of the quality of TB medications (drug company, quality assurance). Team members also confirmed that the correct doses of medications were being given to patients during the DOT process.

### **Observation of Wat Tham Kraboc Program**

Team members visited Wat Tham Kraboc to observe the Hmong refugee camp, reviewed cases with the IOM TB consultant, toured the laboratory at the Wat, and conducted interviews with IOM staff and patients.

### **Key Informant Interviews**

Team members created interview tools for key IOM staff including the Regional Medical Officer, panel screening and treating physicians, DOT workers, and nursing staff (see Appendix 3). Team members interviewed key informants using the abstraction tools.

# Results

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## Observations - Screening Process

**Tuberculin Skin Test (TST)** – TST placement and reading were not observed because TSTs are placed only on Wednesday morning and are read on Friday morning. Interview with nursing staff revealed that there is no formal training or education for TST placement and reading, other than on-the-job training from the supervising nurse.

**Panel Physician** – Our visit to the Pha Wo hospital revealed that panel physicians see approximately 35 to 40 patients per day. Several panel physicians are involved in the screening and treatment of refugees at any given time. The physicians are assigned the duty of either screening or treatment. Screening physicians perform the initial overseas exam and then refer the patient to the treating physician if there is concern for active TB. The treating physician then makes the decision with regard to active TB treatment. Panel physician interviews revealed that the most important needs for the TB screening program were laboratory support and database management. Furthermore, they believe that staffing will need to be increased to ensure the timely processing of refugees during the migration process.

**Radiology** – All patients 15 years of age and older received chest radiograph screening performed at Pha Wo hospital. Children under 15 received chest radiographs only if TST-positive or symptomatic. The radiographs are all reviewed by one radiologist who interprets approximately 100-125 chest radiographs per day. The readings are given to the panel physicians within one day.

**Sputum Collection** – All patients with abnormal CXRs and/or TB symptomatology, as assessed by the screening panel physician, submit three sputum specimens. The patients are shown a sputum collection video prior to appearing for sputum collection. These patients are notified to appear at the sputum collection area which is an outdoor facility with numerous sputum collection stations. A nurse calls each patient and verifies his/her identity. A pre-labeled sputum collection container is given to the patient. A trained laboratory technician then takes the patient to the sputum collection station and aids in the collection of an adequate specimen. The specimen is then placed in a plastic bag in a cooler and transported to the laboratory.

## Observations - Management of TB Cases

### Isolation

When patients are diagnosed with active pulmonary TB, they are transferred to an area that is at the far southwest part of the camp, known as the TB Village, which is overseen by MSF. On our visit to the site, team members observed the following:

There is a 500-yard, steep footpath up the hillside to the Village itself. There is a storehouse where food and medications are kept. The housing units themselves are thatch-roofed bamboo huts, each of which is divided into six rooms opening onto a veranda. The TB Village is divided into three sections. Huts for smear-positive patients are in parallel units to the left of the footpath, smear-negative patients are housed in units to the right of the path, and MDR TB patients are housed in single-room units at the very back of the village. There are two small cafes, one which is to be used only by MDR patients. All visitors, village maintenance staff, and medical staff are expected to wear an N-95 mask at all times while in the village. If the patient is infirm or a child, one family member is allowed to stay with the patient. If the patient has MDR TB, the visiting family member is asked to sleep in separate quarters.

The first patients detected by IOM's active TB screening (two patients were AFB-sputum-smear positive and one was sputum smear negative but culture positive) were begun on treatment at the IOM building at Mae La camp when they were first diagnosed with TB; they were transferred to the TB Village on the first Thursday after treatment was begun, according to the plan for transfer of patient care that has been established between IOM and MSF.

### **DOT Program**

Team members observed DOT being administered to the three patients already diagnosed at the time of our visit. Patients came to the IOM facility in the camp at 8:00 am. The DOT nurse checked the medication order for each patient and counted out the correct number of pills for each drug into a medicine cup. No combination meds are used. Standard four-drug therapy with B6 was used in every case. Medication dosages were verified as correct per patient weight. The patients were observed swallowing the meds, followed by a drink from a small glass of water. Side effects were inquired about after the patient had taken the meds. That DOT administration was then recorded on the DOT sheet. Symptom review is recorded on the DOT sheet weekly. DOT is given 6 days a week. For Sunday a packet is made up and given to the patient on Saturday to be taken the next day.

The DOT nurse stated that she had worked for IOM previously in the Hmong resettlement and the Tham Hin resettlement. She stated she had received no specific training about DOT management but had learned all she needed to know on the job. She would have liked to have had more specific training initially and felt that any new DOT nurses would benefit from initial training.

### **Family Contact Evaluation**

Family units are evaluated together during the medical screening. The x-rays of each family member who is required to have radiography are available at the time of the family members medical screening. If the panel physician feels that an x-ray indicates possible TB, any additional testing for these family members not already routinely done can be ordered (i.e., an AP and lateral x-ray for a child with a negative TST). Interviews with panel physicians revealed that the diagnosis of a known or suspected TB case in a family strongly influenced how the physician evaluated other family members;

there was a low threshold to consider treatment for active TB for these family contacts. Physicians expressed reluctance to treat for LTBI only, because of their concern that they might treat early active disease inappropriately with a single drug. Team members did not observe that contacts were being elicited outside the family.

## **Observations – Laboratory Practices**

Mr. Warren Jones is the IOM Laboratory Manager who has led the development of laboratories used for IOM tuberculosis screening activities in Thailand. These laboratories are located in Wat Tham Kraboc (Hmong refugees), Pha Wo Hospital at Mae Sot (Burmese refugees), Mae Sot General Hospital at Mae Sot (Thailand regional tuberculosis control activities), and Bangkok (for screening of applicants for immigration to the United Kingdom). In addition to his duties for IOM, the laboratory manager has been contracted by DGMQ to provide laboratory expertise in support of the implementation of the 2007 TB Technical Instructions. His responsibilities for CDC include assisting with the development of new TB laboratories in Ho Chi Minh City, Vietnam, and Ciudad Juarez, Mexico; reviewing the TB laboratory at St. Luke's Extension Clinic in Manila, Philippines; and undertaking regional laboratory site visits and evaluations in Asia. These obligations for DGMQ are expected to constitute the majority of his time. IOM has recently hired a new laboratory supervisor for Thailand, who will assume some of the laboratory manager's IOM responsibilities

## **Observations – Training and Education**

### **Staff Training**

#### **Nurse / Outreach Worker Training**

Other than providing guidance on the Technical Instructions (TI) and IOM procedures, no other training is provided to nursing, outreach worker, or technician staff. Health-care workers are expected to come to the job with skills from their specific academic training, such as skin test application and reading; no additional training is provided. On-the-job training is emphasized as the standard for staff training. The IOM nurse responsible for administration of directly observed therapy (DOT) indicated that initial training on general TB information, patient adherence and counseling, management of medication side effects, and contact investigation would have been more beneficial than just learning on-the-job. This training would have also resulted in more rapidly acquiring the needed essential knowledge and skills.

#### **Medical Clinician Training**

Several of the physicians have attended the Denver (i.e., National Jewish Hospital) TB Clinical Course. The staff who attended the course described its benefits, specifically training to recognize the clinical presentation of TB, sharing of complicated case presentations, and training in radiographic interpretation. Other clinical training included participation in a course at the World Health Organization's MDR TB Training Center in Latvia. In addition to training, staff indicated the need for ongoing medical

consultation in regard to TB diagnosis and treatment, particularly for challenging drug-resistant cases.

Other IOM staff attended the 5-day Program Managers Intensive course at the Francis J. Curry Center in San Francisco. This course also included clinical presentation of cases and discussion of radiographic interpretation.

### **Radiologist Training**

IOM contracts for the services of a panel radiologist. The radiographic review performed by the evaluation team found some inconsistencies in interpretation of radiographs between the panel radiologist's report and the findings of the reviewers. This inconsistency was greater in the review of radiographs interpreted at the Tham Hin camp than at the Mae La camp.

## **Refugee Education**

### **TB Education**

IOM conducts life skills training for TB and HIV/AIDS prevention for refugees scheduled for relocation. This educational session is conducted by the IOM health educator. For the refugees at camp, a Karen resident of the camp served as the translator for the session. The session covers TB transmission and pathogenesis, with visual and aromatic teaching aids (the aromatic teaching aid is an air-freshener spray used to demonstrate airborne transmission of *M. tuberculosis*). Patients were actively engaged in the session; however, the educator and other IOM staff indicated that this educational session does not appear to resonate with the audience who do not feel at risk for TB. Additionally, information on dental cleaning is provided as an introduction to producing a sputum specimen. Proper breathing and posture for sputum specimen production were demonstrated by the health educator. HIV risk reduction is included in the training session, with emphasis on the proper use of condoms.

Education, training, and coaching on sputum collection are provided for refugees who must produce a specimen. As stated previously, general information on this is included in the life skills training session. Additionally, a videotape developed specific for this population is shown to these refugees regarding how to produce a sputum specimen. When a refugee is asked to produce a sputum specimen, a technician is assigned to watch and provide coaching.

Individual TB education is provided by the TB nurse for refugees with diagnosed active or suspected active TB disease. In interviews with several of these patients, all were able to provide accurate information regarding knowledge of TB treatment and cure. This indicates that the nurse utilized the "teachable moment" to provide TB information when the patient was highly motivated to learn.

## **Cultural Orientation**

A Cultural Orientation training course was established in Thailand for refugees bound for resettlement to the United States. It is a flexible curriculum that is adapted and updated as needed to match the client group needs. This 5-day course includes role plays, problem-solving activities, and practice of new skills such as making eye contact when greeting someone, as well as general information about the migration process, housing, education, employment, and available resources.

Bulletin boards are placed in central locations in the camp to inform refugees of U.S. customs and norms including holidays, common foods, transportation options, housing, and leisure activities. Also included are photographs and letters from refugees who are now relocated in the US to share their life experiences. These bulletin boards appear to be very popular with the refugees.

IOM produces a one-page (two-sided) newsletter with photographs and information about the relocation process. This newsletter is printed in both Karen and English.

## **Observations – Case Detection**

### **Case Finding Among Mae La Camp Residents in AMI Primary Care Clinics**

A team member interviewed the medical director of Aide Medicale Internationale (AMI) Outpatient Department (OPD) at their facility on Thursday May 2, 2007. In Mae La Camp AMI conducts two OPDs, in Zones 2 and 3, and one inpatient Department (IPD), in Zone 3. The capacity of the IPD is 150 beds. There are approximately 10 new admissions each day, and the monthly census is approximately 700 cumulative patients. Limited laboratory services are available at the site, and radiographic services are performed at Mae Sot General Hospital.

Each of the two OPDs sees from 250 to 400 patients each day. Thirty-three medics work under the physician Director. The two clinics treat over 1000 respiratory infections each month, half of which occur in children <5 years of age. Approximately half of respiratory infections are likely lower tract infections, mostly pneumonia. Uncomplicated pneumonia is managed clinically, without x-rays.

Patients identified as TB suspects on the basis of symptoms of cough >2 weeks, weight loss, or hemoptysis, submit three sputum specimens for AFB, one each on consecutive days. Smear-positive patients are sent for chest x-ray and are referred to the TB Village, under management of a Medecins Sans Frontieres (MSF) team, for housing and treatment.

Suspects with negative smears are managed clinically, with appropriate treatment for other respiratory tract infection, including hospitalization, if severely ill. Patients who do not improve after a course of antibiotics are sent for chest x-rays. They may receive another set of AFB smears and enter the algorithm for diagnosis of TB. In this process they may also receive a diagnosis of smear-negative TB.

The AMI IPD and OPDs detect around five cases of TB each month, approximately half in camp residents and half in persons who are not camp residents but attend the clinic seeking medical care. All are offered care and treatment at the MSF TB Village. Those who refuse to live in the TB Village are not offered self-supervised treatment medications.

HIV infection is diagnosed based on passive surveillance among persons with symptoms and also through the Mae La camp voluntary counseling and testing program. There are currently 70 patients with HIV infection under observation in the camp, 47 receiving antiretroviral drugs through an AMI clinic. In addition, 10 children <18 months of age, born to HIV-infected mothers, are also on antiretroviral drug treatment, awaiting retesting at 18 months of age.

The AMI smear microscopy laboratories are located with the OPD facilities. The facility visited by team members in Zone 3 has two binocular microscopes, each with reflecting light source. That lab collects, processes, and examines 7-12 smears each day, 250-300 each month, and identifies 2 to 3 smear-positive patients each month.

## **Observations – Pharmacy Practices**

Data collected on Thursday, 3 May 2007, at the office of the Chief Nurse, 6<sup>th</sup> floor at the Pha Wo hospital in Mae Sot.

**Key informant:** Chief Nurse. Dr. Tom O'Rourke provided some confirmation. The language barrier between the team member and the Chief Nurse was a potential confounder.

All antituberculosis medications are procured as needed from a central IOM source in Bangkok, with orders placed when the monthly inventory check shows that supplies have gotten low (no particular threshold). These medications are stored on a single shelf in a metal cabinet that has a lockable handle; the cabinet was unlocked throughout this visit. The key to the cabinet is left on the Chief Nurse's desk. Her office is unlocked during business hours and locked after hours. The same cabinet also stores all routinely stocked oral medications that do not require refrigeration, on other shelves. The ambient temperature in the room was 78°F, with air conditioning, which is backed up by emergency generators at the hospital.

The monthly inventory sheet, which is a flow sheet with check boxes, is kept in paper copy only on a clipboard in the Chief Nurse's office. It tracks all medications in the cabinet, not just antituberculosis medications. The Chief Nurse said that "usually" the inventory sheet is updated monthly.

When a nurse has patients on any particular medication, he or she collects it from the cabinet and stocks her plastic basket (this was demonstrated). Depending on the medication and the circumstances, the medications are taken in bulk (i.e., an entire bottle)

or counted out into smaller bottles from a bulk bottle. Removing medications from the cabinet does not involve any recordkeeping (i.e., no sign-out log is involved).

Isoniazid, rifampin, pyrazinamide, and pyridoxine are carried by the nurses in bulk bottles; ethambutol is removed from the single bulk bottle in the cabinet and carried in the plastic basket in smaller containers. The chief nurse said that the antituberculosis medications are repacked by the treating nurse into plastic baggies for daily doses as an ad hoc form of pre-packs.

The medications were all labeled under the names of Thai pharmaceutical companies:

- Sandoz: Rifampin syrup.
- MOMRC: Rifampin capsules, both 300 mg and 450 mg.
- Patar Labs: Isoniazid tablets, 100 mg only.
- Atlantic Lab Corp: Pyrazinamide 500 mg.
- Pharma: Ethambutol 400 mg.

All medications were stocked in abundant supply (enough for complete regimens for 10 or more patients) except for the ethambutol, which probably could have covered the intensive phase for at least 5 patients. Of bottles randomly checked for expiration dates, the earliest expiration was November 2007, and the others had expirations in 2008 or later. IOM procures its 2nd line drugs from IDA (international dispensary association) in Amsterdam, and only purchases GLC-certified formulations.

### **Tuberculin Reagent**

The tuberculin reagent was labeled as produced at the Queen Saovabha Memorial Institute, Thai Red Cross Society. The solution was bottled in 1.2-mL multidose vials, 10 doses per vial, "10 I.U." per 0.1 ml-dose, preserved with phenol and stabilized with Tween 80. It was stored in 5-vial boxes in an unlocked refrigerator that stored vaccines and cold-preserved medications. The initial report from Dr. Varma is that the Thai tuberculin is prepared from lyophilized PPD supplied by Chiron of Italy and standardized by the Red Cross. The policy and procedures for standardization will be supplied later by Dr. Varma.

### **Summary Comments**

1. The supply of antituberculosis medications is more than adequate at the moment, but the procedures for tracking the supply of these medications are quite relaxed. Conversely, drug supply has never caused problems for the IOM-supervised treatment of tuberculosis. Dr. O'Rourke said that his team could implement record systems for establishing accountability.
2. The source and equivalence of Thai antituberculosis medications remain to be noted for this report. The bioavailability and stability of rifampin syrup (i.e., in general, and not just the Thai product) should be confirmed.
3. The standardization for Thai tuberculin remains to be determined. Dr. O'Rourke would be amenable to obtaining a different tuberculin, if recommended.

## **Observations – Wat Tham Kraboc Visit**

Dr. Melissa Varma, the IOM treating physician for TB, accompanied three members of the team to Wat Tham Kraboc. Team members observed that there were only a few remaining Hmong refugees still at the Wat, living in houses that had little light or ventilation. There are now 12 MDR TB patients still on treatment at the Wat, many of whom are scheduled to complete treatment for 24 months post culture conversion toward the end of this summer. Team members reviewed the cases of seven patients with Dr. Varma. Treatment regimens were appropriate; all patients were on at least 4 anti-TB medications to which their isolate was sensitive. The injectable agent used at the Wat is kanamycin, and the fluoroquinolone is ofloxacin. Ethionamide, cycloserine, PAS, clofazimine, Augmentin, and linezolid are available with adequate supplies to complete treatment. One patient had acquired fluoroquinolone resistance, but no patient had XDR-TB. Every dose of medication is administered by DOT. Team members observed the weekly supplemental ration of meat, eggs and rice being dispensed to MDR TB patients and their families as an incentive to continue treatment.

Team members spoke through a translator with one patient. He requested our opinion on the treatment he was receiving and wanted to know if he still required treatment. This patient had initially been treated with IRZE in 2004. Drug-susceptibility results were not available at that time. He did not improve on treatment, remaining smear and culture positive. In February 2005 he was begun on second-line therapy with cycloserine, ethionamide, ofloxacin and kanamycin, with the oral drugs given three times a day. Only the morning dose was observed and the patient later reported that he did not take his self-administered doses. DST results from his January isolate returned in June and showed resistance to all first-line agents but sensitivity to the second-line agents. His sputum had converted to negative in April and he had improved clinically. He was changed to a fully supervised twice a day regimen in June 2005. Over the following year, he again worsened clinically and radiographically, and one of three sputum samples in March 2006 grew an isolate found on DST to be resistant to ofloxacin. He is currently on kanamycin, ethionamide, cycloserine, linezolid, clofazimine and Augmentin. He has been smear and culture negative for 8 months. He has predominately right-sided pulmonary disease with residual cavitation in the RUL. Team members felt he was potentially a good candidate for resection surgery as his best chance of cure, and this recommendation will be made to the patient.

Reviewing this case and the six others showed the critical importance of timely culture and DST reporting. Delays of several months for first-line DST results and up to 6 months for second-line DST results during the screening of the Hmong refugees at WTK prior to their resettlement in the USA, prompting IOM to develop in-house capacity at WTK to perform first-line DST, and now at Mae La, to also begin second-line DST.

A review of laboratory results of mycobacterial cultures at WTK revealed that 8 of 65 persons with positive cultures on LJ medium grew in the seventh week of incubation. These persons would have been missed if cultures had been discarded at 6 weeks. Drug susceptibility results of positive cultures from the IOM lab at Wat Tham Kraboc were

repeated at the supranational laboratory in Brisbane, Australia and results correlated closely.

## Data - Review of Tham Hin Data

### Smear, Culture, DST, and TST Results of Screened Refugees

IOM data on the screening program for refugees from Burma in the Tham Hin camp in 2006 yield valuable information on the implementation of revised DGMQ Technical Instructions to include culture and drug susceptibility testing in addition to AFB smears in the evaluation of TB cases and TB suspects, and in addition, tuberculin skin testing of refugees over the age of 6 months.

Table 2 indicates that almost 30% of the 4,686 persons screened in that program were classified as TB suspects, and that TB, almost all of it pulmonary, was diagnosed in more than 5% of refugees screened.

**Table 2.**  
**TB Screening**  
**Tham Hin Camp, Thailand**

<b>Category</b>	<b>N(%)</b>
<b>Number of individuals screened</b>	4,686 (100)
<b>Number of suspected TB cases</b>	1,375 (29.4)
<b>Number diagnosed with TB</b>	252 (5.4)
<b>Pulmonary cases</b>	251 (5.3)
<b>Extrapulmonary cases</b>	1 (.02)

Among the 251 cases of diagnosed pulmonary TB, only 7 (2.8%) had positive AFB smears (Table 3). Among those, four were also culture-positive. An additional 24 cases were diagnosed in smear-negative patients because of the availability of cultures. The availability of culture therefore increased the yield of TB diagnosis among screened refugees by over three-fold in comparison to sputum smear alone. However, Table 3 also indicates that the majority of TB cases among screened Tham Hin refugees were not confirmed by bacteriology, either smear or culture. The diagnosis in these cases was made on the basis of radiographic abnormality with or without symptomatology.

**Table 3.**  
**Basis of TB Diagnosis Among Pulmonary Cases**  
**Tham Hin Camp, Thailand**

<b>Cases of Pulmonary TB</b>	<b>N (%)</b>
<b>Initial sputum examination</b>	251
<b>Smear +/Culture +</b>	4 (1.6)
<b>Smear - /Culture +</b>	24(9.6)
<b>Smear +/Culture -</b>	3 (1.2)
<b>Smear -/Culture -</b>	220(87.6)
<b>Smear/Cultures not performed</b>	0 (0.0)

Drug susceptibility testing was available on all 28 culture-positive cases (Table 4). Most cases (85.7%) were susceptible to all first line drugs. Three cases (10.7%) of isoniazid-resistance were found, and one case (3.6%) of MDR TB was found.

**Table 4.**  
**Results of Drug Susceptibility Testing of Culture-Positive Pulmonary TB Cases,**  
**Tham Hin Camp, Thailand**

<b>Cases of Pulmonary TB</b>	<b>N (%)</b>
<b>Culture-positive pulmonary TB</b>	28
<b>DST results documented</b>	28 (100)
<b>- MDR TB</b>	1 (3.6)
<b>- Poly drug-resistant TB</b>	0
<b>- Monoresistance TB (Isoniazid)</b>	3 (10.7)
<b>- Pansensitive TB</b>	24 (85.7)

Table 5 shows the excellent treatment outcomes for refugees screened at the Tham Hin Camp. All cases received DOT and over 95% completed treatment. The default rate was negligible.

**Table 5.**  
**Outcome of TB Treatment of Refugees.**  
**Tham Hin Camp, Thailand**

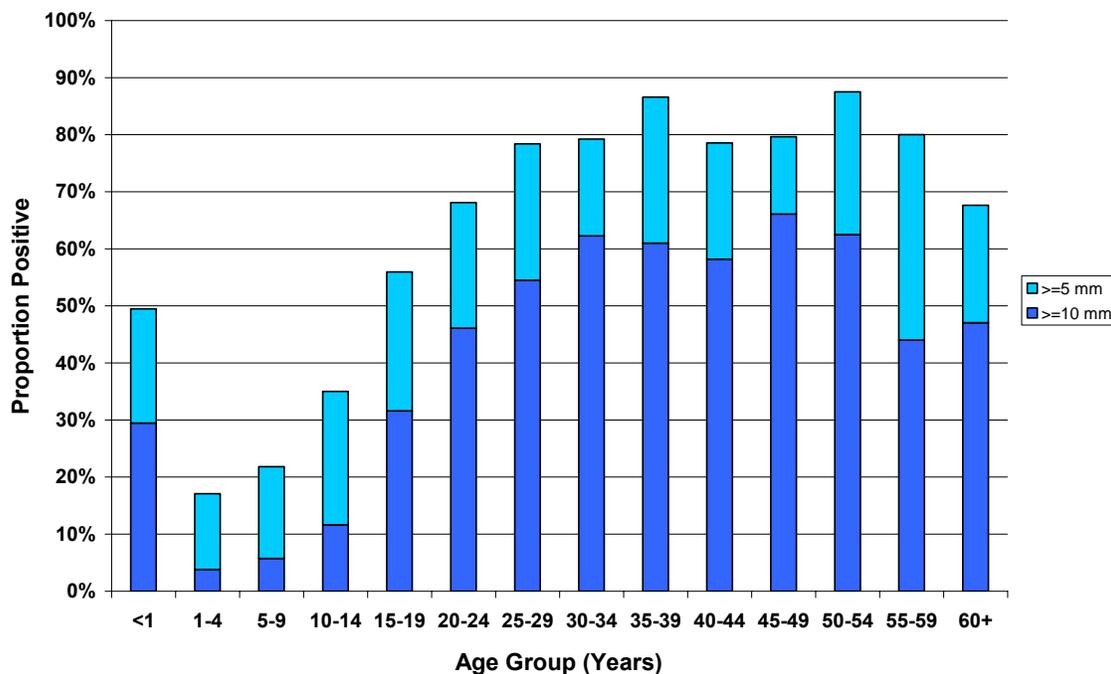
<b>Cases of Pulmonary TB</b>	<b>N (%)</b>
<b>All cases of TB ( culture +/-)</b>	252
<b>Received DOTS</b>	252 (100.0)
<b>Completed treatment</b>	241 (95.6)*
<b>Defaulted</b>	1 (0.4)
<b>Death prior to TB completion</b>	2 (0.7)
<b>Departed to U.S. before Rx completion</b>	1 (0.4)**
<b>Relapsed</b>	0

\* Some patients continue on treatment in Thailand

\*\* Cleared by DGMQ and notified to U.S. receiving state before relocation

Data were also accumulated on skin test reactivity among Burmese refugees at Tham Hin Camp, because under revised Technical Instructions all refugees screened there received TST as well as chest radiograph. The results of TST testing of refugees, separated into 5-year age groups, birth to 60+ years, indicated several interesting facts (Figure 4). First, almost 50% of children  $\leq 1$  year of age had reactions  $\geq 5$  mm, most reasonably explained by a BCG effect. Then reactivity decreased among those 1-4 years, as only 3% had reactions  $\geq 10$ mm. Beyond that age, reactivity increased through age group 30-34 years, to 62%. After that, reactivity stabilized at around 60% until the older age groups. During the period of linear increase, the graph indicated that the annual risk of TB infection was almost 2%.

**Figure 4**  
**TST Results, Tham Hin Camp,**  
**Through March 2007**



In summary, the IOM screening and treatment program for Burmese refugees at the Tham Hin camp in 2006 yields valuable information on the revised Technical Instructions. Most notably, the program showed that the addition of culture and drug susceptibility testing augments the previous smear-based diagnostic program to a considerable extent, adding valuable surveillance, diagnostic, and treatment data. For example, availability of culture increased the diagnostic yield of cases by at least 3-fold over smear alone (7 smear-positive cases, 28 culture-positive cases). If culture is used as the gold standard diagnostic procedure, then the increase in yield with culture is 7-fold (4 cases diagnosed via smear, 28 cases diagnosed via smear plus culture, Table 3). DST results showed that only one MDR TB case was encountered in this screened population of refugees, indicating that the prevalence of drug resistance might be substantially less than that reported at WTK.

Even with the availability of culture in addition to smear, the vast majority of TB cases in this screening, 88%, were diagnosed on the basis of radiographic abnormalities among persons who had negative bacteriology results (Table 3). This observation, which the evaluation team believes represents unnecessary treatment of persons without TB disease, was discussed in detail with the IOM team who conducted the Tham Hin program (who are now working at the Mae La camp). Reasons were explored and possible solutions were proposed and discussed.

### **Pediatric Case Review**

Team members met with the treating physician (Dr. Yen) now at Mae La camp, who had been previously at the Tham Hin resettlement. Summary information about all 88 pediatric cases (i.e., patients < 15 years of age) was reviewed and six selected cases were discussed in detail. These 88 cases represented 32% of all TB cases diagnosed in the Tham Hin resettlement; 75% were household contacts of TB patients. 37 were younger than 4 years of age and 51 were 4-14 years old. There were no positive culture results despite the collection of three sputum specimens or gastric washes from all children. Overall, 87.5% were TST negative (less than 5 mm). Adenopathy was infrequently found.

One case reviewed in detail was the 10-month-old contact of a culture positive TB case. The child had a 0 mm TST and an x-ray that was read as normal. This child had normal weight and occasional cough and was started on INH for LTBI treatment. While on INH, the child had developed recurrent cough and was admitted to hospital with pneumonia. He did not gain weight and continued to have slight rales and rhonchi on the left side of the chest. He was then started on four-drug therapy and was felt to improve with no recurrence of cough and with a 2-kg weight gain. On retrospective review, there was probable right paratracheal adenopathy present on the original film.

One additional case in a 13-year-old showed hilar adenopathy bilaterally, but the other four cases had x-rays which on review showed nonspecific findings only.

### **Random Chart Review – Tham Hin Camp**

Of the 254 TB cases diagnosed at Tham Hin camp, 17 cases were reviewed by three reviewers, seven with chest radiographs and ten without. Of the seven cases that had radiographs to review, six were clinical smear and culture-negative cases and one was a culture-confirmed, smear-negative case. Two of the cases occurred in children under age 15 and five occurred in adults.

The three reviewers agreed with the management of two cases, one smear- and culture-negative case that had clinical and radiographic improvement on treatment and one culture-confirmed case occurring in a 24-year-old patient.

The reviewers disagreed with the management of three cases that were classified as smear- and culture-negative cases; these cases were classified by the reviewers as inactive TB. In one instance there was partial agreement with the management of the case, a 9-year-old asymptomatic child with negative TST who was initially classified as a TB suspect, but then reclassified as not a TB case after 2 months of treatment. The reviewers would not have initially classified the child as a TB suspect because there was disagreement with the interpretation of the initial CXR as being abnormal, but agreed with the reclassification of the case.

Reviewers were unable to evaluate one case because of discrepancies between two different forms (the immigration form and the internal chemotherapy form in the patient's IOM chart) with regard to symptoms and TST results.

An additional ten cases without CXRs were reviewed by two reviewers. Six of ten (60%) of cases occurred in adults and 4 (40%) occurred in children. One case (10%) was culture positive and the other 9 (90%) were smear- and culture-negative clinical cases. The reviewers agreed with the management of five (50%) of the cases and disagreed with the management of the other five cases. This analysis relied upon proper interpretation of chest radiographs by the radiologist, as the reviewers were unable to independently judge the chest radiograph readings. TSTs were positive in five (50%) cases and negative in the 5 .

Overall, reviewers noted an overdiagnosis of smear- and culture-negative cases in adults that then triggered the identification of numerous child contacts to smear and culture-negative cases. This led to overdiagnosis of smear- and culture-negative cases in children. In two charts final reports on cultures were recorded on end-of-treatment sputum specimens that had not yet been collected and/or processed. On further discussion with IOM staff team members learned that this was done because the agency responsible for managing refugee travel (known as the Overseas Processing Entity) required that all forms be complete before they would begin arranging travel. Team members were assured that if end-of-treatment smears or cultures were positive, the refugee travel would be rescinded.

## **Data - Early Data from Mae La**

Screening at Mae La camp began on April 9, 2007. Team members were able to review the results of the first 3 weeks of screening, during which 1,300 refugees were screened. Three sputum specimens were obtained from each of 97 refugees because of abnormal x-ray findings and/or symptoms. Of these, two refugees had at least one positive AFB smear. This is an initial smear-positivity rate of about 150/100,000, which suggests that the burden of TB disease is likely to be very similar to that of Tham Hin. An additional refugee who was AFB smear negative on 3 specimens is already confirmed culture positive.

There were 107 children who had TST testing done (Note: for the initial 2 weeks, TST testing was performed on children  $\geq 6$  months through 5 years of age, according to the Technical Instructions issued by the State Department on January 16, 2007. After the first 2 weeks the screening algorithm was changed according to the 2007 new Technical Instructions, which specified that children aged 2 through 14 were TST tested.) Overall, 15% of children tested had a TST  $\geq 5$  mm.

## **Data – Current Mae La Cases**

At the time of the Team's visit, three TB cases were detected from the initial screening process from April 9 through April 27 2007; two that were smear-positive and one that was smear-negative, but culture-positive. No patients had been started on treatment without bacteriologic confirmation. The reviewers were told that all three patients had been HIV tested, but the results were not found in the patient records.

### **Case # 1**

#### **Case Summary:**

50-year-old asymptomatic previously healthy Karen male who was found to have an abnormal chest radiograph showing a LUL infiltrate during the refugee screening process (confirmed by the evaluation team). No prior history of TB, TB treatment or TB exposure. The patient submitted three sputum specimens on March 26, March 27 and March 28, 2007. All three AFB smears were negative, but the culture from the first specimen was reported to be positive for *M. tuberculosis* complex in liquid media by the GenProbe method on April 19, 2007. The patient was started on a standard four-drug treatment regimen consisting of INH 300 mg po qd, RIF 600 mg po qd, EMB 1200 mg po qd, PZA 2000 mg po qd, and Vitamin B6 10 mg po qd by full DOT on April 23, 2007. He was isolated in the TB Village on May 3, 2007. He continued his work as an HIV counselor in the VCT program at AMI from the date of diagnosis to the date of isolation.

#### **Patient Interview:**

Patient # 1 had a good understanding of the definition and the concept of tuberculosis disease, but because he was asymptomatic, he did not think that he had active tuberculosis. He knew that TB was transmitted through the air and was concerned about his family, but was resistant to the idea of being isolated in the TB Village. He did finally agree to going to the TB Village until culture conversion. The patient was most concerned about his wife and 19-year-old son being delayed in going to the United States. He already had family living in the United States and asked whether his wife and son could go to the United States before him. The patient was doing well with his medications and reported no side effects after two weeks of treatment.

### **Case # 2**

#### **Case Summary:**

61-year-old asymptomatic previously healthy Karen male who was found to have an abnormal chest radiograph showing a RUL fibronodular infiltrate. No prior history of TB, TB treatment or TB exposure. The patient submitted three sputum specimens on 4/18, 4/19 and 4/20/07. All three AFB smears were positive and the patient was started on a standard four-drug treatment regimen consisting of INH 300 mg po qd, RIF 450 mg po qd, EMB 600 mg po qd, PZA 1250 mg po qd and Vitamin B6 10 mg po qd by full DOT on 4/23/07. He was isolated in the TB Village on 5/3/07. Eight family contacts had yet to be evaluated.

**Patient Interview:**

The patient, who had a 9<sup>th</sup> grade level of education, had a reasonable understanding of tuberculosis. He said that ‘TB causes fever and cough’ and that TB is transmitted through ‘cough and eating together’. A friend with TB had told him about the disease and he was certain that it could be cured if he took his medications as prescribed. He had been told that he would receive ‘‘at least 6 months’’ of treatment for TB and that he would remain isolated in the TB Village for ‘‘at least 2 months’’. The patient stated that he was doing well with his medications without any side effects and that he agreed with his diagnosis. He stated that he had no concerns as long as his disease was ‘‘cured.’’

**Case # 3****Case Summary:**

57-year-old previously healthy Karen female who presented to the AMI facility with chief complaint fever and cough for 8 months. No prior history of TB, TB treatment or TB exposure. A chest radiograph showed a right subpulmonic pleural effusion and the patient submitted three sputum specimens on April 18, April 19 and April 20, 2007. She was referred to IOM after her providers learned that she was a U.S.-bound refugee. All three AFB smears were positive and the patient was started on a standard four drug treatment regimen consisting of INH 300 mg po qd, RIF 450 mg po qd, EMB 600 mg po qd, PZA 1250 mg po qd and Vitamin B6 10 mg po qd by full DOT on 4/24/07. She was isolated in the TB Village on 5/3/07. Five family contacts had been evaluated for TB.

**Patient Interview:**

The patient, who had a 4<sup>th</sup> grade level of education, had a poor understanding of her disease. She said that ‘‘tuberculosis causes cough’’, but she stated that she knew nothing about transmission and had not been told anything else about the disease. She had been told that she would receive ‘‘at least 6 months’’ of treatment for TB and that she would remain isolated in the TB Village for ‘‘at least 2 months’’. The patient stated that she was doing well with her medications without any side effects and that she agreed with her diagnosis. She had no concerns at the time of the interview.

**DOT Observation**

The DOT administration of medications was observed for all three of the above patients. Medications were given as described in the previous section (see DOT section of this report). All doses were found to be in the recommended range for weight. Team members did not confirm how the half-pill doses were accomplished. The only recommendation would be to ask about side effects prior to administering the medications.

## **Data - Radiology Review Results**

Fifteen chest radiographs at Pha Wo hospital were selected by the IOM physicians for review from among all the patients who had had sputum examinations ordered. Three reviewers independently reviewed the films blinded to the radiologist's interpretation. There was agreement in the reading of the films among the three reviewers in 14 out of 15 cases. There was agreement between the overseas radiologist's readings and the readings of the three reviewers in 13 out of 15 cases. Two of three reviewers agreed with the decision for sputum collection based on the radiographic interpretation in 12/15 cases. One reviewer agreed with the decision for sputum collection in 7/15 cases. Overall, the quality of radiographic interpretation was high. The technique used during the shooting of radiographs was good in 7/15 cases and intermediate to poor due to over and underpenetration in the other 8 cases. Five of 15 chest radiographs showed bilateral disease; 7/15 chest radiographs showed unilateral disease and 3/15 chest radiographs showed a non-TB abnormality or an abnormality not consistent with active TB. No chest radiographs showed either bilateral extensive or cavitary disease.

## **Conclusions**

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### **Burden of TB in Burmese Refugees**

From the data available to us from Tham Hin camp and the very preliminary results from Mae La, the burden of TB disease among the Burmese refugees on the Thai – Burmese border is not less than among the Hmong refugees from Wat Tham Kraboc. Of 4,686 refugees screened at Tham Hin, 28 were culture positive, for a case prevalence rate of approximately 600 culture-positive TB cases per 100,000 population . The comparable figure for Wat Tham Kraboc after routine sputum-culture testing was done was 500 cases per 100,000. The smear-positivity rate in the Tham Hin screening was 150 cases per 100,000, again very similar to Wat Tham Kraboc. In the initial 3 weeks of screening at Mae La camp that were available for evaluation at the time of the site visit, two of 1,300 refugees screened were AFB smear-positive, for a smear-positivity rate of about 150 cases per 100,000. In addition, one smear-negative patient had already been found to be culture-positive.

A striking difference from Wat Tham Kraboc is the difference in the proportion of MDR TB. Whereas the proportion of culture-positive TB cases in Wat Tham Kraboc that were MDR was about 40%, in Tham Hin camp only one (3.6%) culture-positive case was MDR. The team does not know what the incidence of MDR TB will be in Mae La; however, the ethnicity and life experiences between refugees at Tham Hin and Mae La are very similar and might suggest that MDR will not be as prevalent as at Wat Tham Kraboc. The overall incidence of INH resistance at Tham Hin was 14.3% (10.7% monoresistance plus 3.6% MDR).

The burden of TB disease in Burmese refugees thus has been found to be high, with a moderately high rate of INH resistance, but without the extraordinary rate of MDR TB found among Hmong refugees from Wat Tham Kraboc.

## **Overall Assessment of the IOM Screening Program for Refugees in Mae La Camp**

The Team was highly impressed by the IOM program for screening U.S.-bound refugees at the Mae La Camp. IOM has long experience in conducting TB screening among refugees, and that institutional experience shows very clearly in its knowledge of and attention to important details in organization, staffing, clinical acumen, data management, training of staff, and sensitivity to the plight of refugees approaching resettlement, including awareness of specific cultural issues. The organization conducts its business with professionalism and with empathy toward its clients.

Health screening of refugees is a complex endeavor at best, and there are enormous challenges in conducting a successful screening program with demands to process hundreds of persons each week for many months. The acknowledged expertise of IOM in this field was corroborated in many ways during this visit. The Team wishes to offer its congratulations to IOM for doing a difficult job very well, and its best wishes for continued success.

The team also wishes to comment on specific strengths of this program and in particular, to note the specific challenges that it faces, as well as to offer recommendations for improving its already very good performance.

### **Program Strengths:**

- As noted above, members of the medical, laboratory, and program support staff are highly experienced and in general have long tenure with IOM.
- The organization of its clinical, radiographic, and laboratory components, which are all located on one floor of Pha Wo Hospital in Mae Sot. This close proximity of the essential screening components lends itself to efficiencies in patient processing, clinical decision making, and information sharing, as well as promoting collegiality among the IOM team.
- The patient and specimen tracking systems appear to be exemplary.
- The information technology and data management systems are advanced and efficient.
- The treatment program for patients with TB, including the DOT component, is very well-organized and is patient centered.
- The sputum collection process, which is an essential component of this screening and treatment program utilizing smear microscopy and culture, is especially commendable. The education of patients and training of staff in their roles are especially impressive.

- The isolation facility for infectious patients in the TB Village is a very effective tool for TB control in the community and prevention of spread in families.
- The cooperation and collegiality among the staffs of IOM, MSF, and AMI are admirable.

### **Challenges to the IOM Program:**

- Radiologic interpretation of chest radiographs. The medical staff has pointed out weaknesses in professional radiology consultation on problematic chest radiographs. This resource is viewed as essential to good clinical decision making, particularly in this setting in which the clinical evaluation of patients' symptoms and signs is not ideal.
- Turn-around time for drug-susceptibility testing. Delayed availability of DST results was noted as a serious issue in patient management at the IOM Wat Tham Krabok screening and treatment program. The problem may well have been addressed by locating the laboratory for DST on site at Mae Sot. Nevertheless, turn-around time for DST in this program should be closely monitored.
- Access to DST for second line anti-TB drugs is a potential problem, one that was encountered especially at the Wat Tham Krabok program. The arrangements now being made to work closely with the Brisbane, Australia laboratory to provide such testing, and the eventual plan to establish a second-line DST program at the IOM lab in Mae Sot, should be monitored.
- There is uncertainty among IOM panel physicians and treating physicians about the guidelines and expectations in management of smear- and culture-negative TB, extrapulmonary TB, and family contacts of infectious TB cases. These issues were subjects of extensive discussion among staff and Team members, and recommendations for clarification are included in this report.

### **Overall Assessment of the New Technical Instructions on Refugee Screening in Thailand**

For many years health professionals working in TB control in the U.S. have discussed and debated the feasibility of adding culture and drug susceptibility testing to the process for screening refugees and immigrants who immigrate to the U.S. The process used since 1991, in which the evaluation of applicants for immigration was based on chest radiography and sputum smear examinations, including the prolonged clearance period granted between the time of the examination by panel physicians abroad and the time of immigration, was clearly suboptimal by U.S. standards of diagnosis of active TB, and there were many documentations of instances in which persons with active tuberculosis came through the system and immigrated legally. Such cases placed family members and other close contacts at risk of TB infection and disease, as well as persons traveling on prolonged airline flights with them, and ultimately, U.S. citizens who were exposed after arrival. In addition, the immigration of persons with active TB placed an additional burden of responsibility and work on TB control programs in the U.S.

Given these documented disadvantages of the chest radiograph- and smear-based system, there was acknowledgement that in most places where panel physicians and programs were conducted the technical challenges of establishing a laboratory capable of culturing

and conducting DST on mycobacteria, or the lack of opportunity to link conveniently with such an existing laboratory, made it unfeasible to impose the requirement for mycobacterial culture into the screening process.

The scenario described above changed dramatically with the detection in 2005 of an outbreak of MDR TB among a group of 15,000 Hmong refugees living in Thailand at Wat Tham Kraboc who were being screened by IOM prior to resettlement in the U.S. MDR TB was found in extremely high incidence in that population, with cases being detected both at the camp during the screening process and in the U.S. after resettlement. The latter finding led to an emergency assessment and response on the part of CDC DGMQ and DTBE, in cooperation with IOM. As a part of that response, a new screening algorithm was instituted (referred to as the final Hmong algorithm) which included mycobacterial culture and DST specifically for that screening program (see Background, “2007 New Technical Instructions for Tuberculosis Screening Treatment” of this report). This was possible because IOM had already established laboratory capacity for mycobacterial culture in Thailand, and was in fact already using culture selectively in its screening program for U.S.-bound refugees.

Data presented in the Background section of this report show the effect of adding culture and DST to the Hmong screening. Table 1 shows that there was a striking reduction in the importation to the U.S. of active TB cases after the introduction of the final Hmong algorithm. This measure, along with the establishment of an aggressive treatment program for MDR TB, effectively ended the outbreak.

The success of the culture and DST at the Hmong screening prompted DGMQ to continue that screening algorithm at a subsequent screening program for Burmese refugees that was established in 2006 at the Tham Hin refugee camp in western Thailand. In that screening the value of the final Hmong algorithm was clearly established in a non-outbreak refugee screening setting. As shown in Table 3, seven patients from the screened population at Tham Hin camp were detected by AFB smear, but an additional 24 cases were detected among smear-negative patients by culture. This result led to the detection of more than three times the number of cases, allowing treatment for persons with active TB as well as prevention of progression to more advanced smear-positive TB among those persons, with the consequent personal and public health implications.

DST was shown to add an even further positive dimension to screening. Table 4 shows the results of DST of the 28 culture-positive cases from the Tham Hin screening. The findings, including a modest frequency of isoniazid resistance (10.7%) and only one MDR TB case, provided surveillance data that will be invaluable for U.S. TB Controllers, and obviously enabled IOM physicians to select optimal treatment regimens for individual patients.

Though it is too soon to evaluate the effect of culture and DST at the Mae La screening, data will rapidly accumulate there because of the very rapid pace of screening at that site. The Mae La experience with culture and DST in the screening algorithm will thus provide a very timely opportunity to corroborate the value of these new components, and

also to further assess the technical and logistical issues such as specimen collection, transport, contamination rates, and turn around times. Indicators for monitoring the program have been proposed by the Evaluation team, and include elements to monitor culture and DST performance.

During its visit, the Team had numerous opportunities to discuss among itself and with the IOM Regional Medical Officer, Panel Physicians, and Laboratory Director the practical issues of using the 2007 new Technical Instructions for this screening. As a result, a number of areas were identified where clarification and even amendments of those Technical Instructions would be desirable.

During the trip it was pointed out that DTBE, following a suggestion from ACET, had drafted a set of program indicators for the IOM screening program for refugees in Thailand. Based on information gained on-site during this program evaluation, the team prepared a final set of feasible performance indicators on its current screening program, using the new Technical Instructions. This is included as Appendix 2 to this report, and a recommendation is given below to DGMQ on potential usage of these indicators.

The Team believes the data reviewed above from the Wat Tham Kraboc and especially from the Tham Hin screening, although preliminary, suggest the immense value that mycobacterial culture and DST can add to a refugee screening program. The challenges of establishing the laboratory capacity for culture and DST are not trivial and must be addressed (see the Laboratory section of this report), but the Evaluation Team believes that this program allows an intriguing glimpse of the future of TB control among refugees and immigrants and should be thoroughly evaluated and if feasible, aggressively expanded. DGMQ and DTBE are to be commended for adding this interim requirement, ending years of debate about the value of culture and DST in this setting, and IOM is to be especially commended for demonstrating its added value to refugee screening.

## Recommendations

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### IOM Overseas Refugee Screening Program:

#### 1) Laboratory

- a. During the initial period while the laboratory is beginning operations, additional visits by laboratory supervisory personnel are needed. An IOM TB Laboratory manager for Thailand has been hired and should participate in the additional supervisory visits. Regular site visits and conference calls to monitor performance are recommended. Initially, such contacts may be needed several times a month. Additional training of the Pha Wo laboratory manager in monitoring laboratory performance is also recommended.
- b. Patients currently do not rinse out their mouths before providing a sputum specimen. Rinsing out their mouths with good quality, bottled water may help reduce the amount of oral flora that gets into a sputum specimen.
- c. Metal racks instead of Styrofoam racks should be used in the cold chests to improve the cold temperature exchange between the samples and the cold packs.
- d. Although the contamination rates in Lowenstein-Jensen medium are approaching the recommended levels (3% to 5%), additional efforts are needed to reduce the contamination rate in MGIT tubes. Two changes to consider are 1) ensure that all specimens are in contact with decontaminating solution for at least 15 minutes but no more than 20 minutes by processing no more than 10 samples at a time and starting the timer when the specimen in the last tube in a set is vortexed with the decontamination solution, 2) each tube should be inverted several times to ensure that decontamination solution comes in contact with all surfaces of the tube. If these changes are not sufficient to lower MGIT contamination rates to ~10%, one should consider one or more of the following: increasing the final NaOH concentration to 2%, increasing the time to 20 minutes, and increasing the concentration of antifungal agents in the MGIT media.
- e. Prior to installing the second biosafety cabinet, consideration should be given to placing the second biosafety cabinet in the incubator room. It would be desirable, but not essential, if one room could be dedicated to manipulating sputum specimens and one room dedicated to manipulating cultures in order to minimize the possibility for cross contamination. One might be able to free space in the incubator room by moving one or two of the LJ incubators into the specimen processing room. This is just one possible approach to safely manipulating cultures and preventing cross-contamination and IOM staff are encouraged to implement an approach that is feasible and practical in their setting.

- f. The laboratory staff and the clinicians should discuss the information that the laboratory provides to the clinicians. Clinicians should be notified as soon as possible of a positive AFB-smear result and a positive *M. tuberculosis* culture result. Some clinicians find it useful to be notified when growth of an AFB-positive bacterium is detected in a culture. Typically such notification is “Growth of an acid-fast bacterium (AFB) detected. Species identification pending.”
- g. If nontuberculous mycobacteria (NTM) are isolated, consider reporting “NTM isolated” or “Acid-fast bacillus isolated, not *M. tuberculosis*” rather than reporting “contaminant.” This may be important for patient management and may provide a better evaluation of the performance of the culture systems. For example, an increase in isolation of environmental mycobacteria (e.g., *M. goodii*) may signal the need to evaluate specimen collection procedures.

## 2) Pharmacy

- a. Medications should be prepackaged for individual patients for DOT administration to minimize potential medication errors.

## 3) Skin testing

- a. Determine that PPD solution used in IOM program is equivalent to PPD-S and, if not, obtain an internationally recognized PPD that is equivalent to PPD-S for use in the program.
- b. Provide standardized TST training for all staff involved with placement and reading utilizing CDC training materials.

## 4) Medical screening

- a. The team agrees with the decision to implement computed radiography, especially given the observed overpenetration, underpenetration and other technique difficulties.
- b. If a CXR is found to be technically unsatisfactory, the examination should be repeated while the patient is still present.
- c. Panel radiologists should be oriented and trained to recognize and record CXR abnormalities as delineated in the U.S. Department of State CXR and classification worksheet (DS 3024).
- d. Ensure appropriate clinical training in diagnosis and treatment of TB, including radiographic interpretation, for panel physicians per ATS/CDC/IDSA TB treatment guidelines (consider available courses such as National Jewish Med Center or Curry Center TB Intensive). Ensure all clinicians receive Curry self study course in CXR interpretation.
- e. IOM should budget funds for training of panel radiologists and panel physicians as noted above.
- f. CXR findings of solitary calcified nodule or granulomas, pleural thickening, hilar calcification and/or diaphragmatic tenting should not trigger sputum collection if no other abnormality is present on CXR.

- g. If the only finding is blunting of the costophrenic angle, exclude an active pleural process and, if excluded, sputum collection is not required.

**5) Management of patients with an abnormal CXR**

- a. If the physical exam and CXR findings reveal an infiltrate consistent with pneumonia and three AFB sputum smears are negative, then treat for pneumonia and reevaluate the patient clinically after treatment completion and with a CXR 8 weeks after treatment initiation.
  - i. If CXR is improved and patient is well clinically and AFB cultures are negative then clear for travel.
  - ii. If CXR is stable or worse and/or patient has not clinically improved, then consider collecting three additional sputum specimens for AFB smear and culture. Consider starting active TB treatment utilizing follow-up CXR findings, clinical status and TST results to assess the likelihood of active TB and treat accordingly (refer to medical management of culture-negative TB).

**6) Management of smear and culture negative cases**

- a. While the main purpose of TB screening is to prevent the importation of infectious TB, a secondary consideration must be to minimize over utilization of resources and potential harm to individual patients through unnecessary delay in immigration and exposure to TB medications and their potential adverse effects. Therefore:
  - i. If a patient has three negative AFB smears, TB treatment should only be initiated if the CXR and clinical findings are highly suggestive of active pulmonary TB. If AFB culture results are negative on final report for *M. tuberculosis* complex, the patient should be reevaluated clinically, radiographically and with TST and treatment should be continued only if there is evidence of clinical and/or radiographic improvement.
  - ii. Consider treating adult smear- and culture-negative cases with a 4-month regimen (2HREZ, 2HRE) per ATS/CDC guidelines.

**7) Management of extrapulmonary TB**

- a. For a patient with extrapulmonary TB (usually scrofula) and no evidence of pulmonary TB disease, if 4 months of treatment can be given without delaying departure or if withholding treatment would be harmful, then treatment may be started. According to the TIs, if treatment is not initiated and 3 or more months have elapsed, then the validity period of the physical exam and chest radiograph has expired and this evaluation will need to be repeated.

- 8) For this resettlement, the team recommends eliminating routine follow-up gastric aspirate collection in children.** The team also recommends to DGMQ that this requirement be deleted from the Technical Instructions.

## **9) Evaluation and management of contacts**

- a. The definition of a contact is a person who has shared the same airspace in a household or other enclosed environment for a prolonged period (days or weeks, not minutes or hours) with a smear and/or culture-positive pulmonary TB case
- b. The TB skin test should be used in the evaluation of all contacts
  - i. If the contact is TST-positive on initial evaluation and not placed on LTBI, then perform medical evaluation, including CXR, and repeat every 3 months until departure
  - ii. If the contact is TST-negative on initial evaluation and not placed on window prophylaxis then repeat the TST every 3 months\* until 3 months after contact break (defined as either isolation of the case away from the contact OR case culture conversion)
    1. If the contact becomes TST-positive, then perform a medical evaluation, including CXR, and repeat every 3 months until departure with a class B3 status
    2. If the contact remains TST-negative 3 months after contact break, then do not classify as class B3

\* Three months has been chosen to correspond with the requirements for frequency of CXR evaluation

## **10) Training and education – staff and refugees**

- a. Staff training
  - i. Nurses/Outreach Workers - Provide TB self-study modules and training sessions for current staff and all new hires on tuberculin skin test administration and reading, directly observed therapy, patient education and adherence, case management, contact tracing.
    1. Ask patients about adverse effects before the next dose of drugs is given.
  - ii. Panel physicians – Continue to provide opportunities for clinicians to seek clinical training, including the treatment of MDR TB/XDR-TB, via the courses already identified. Provide copy of self-study tutorial “Radiographic Manifestations of Tuberculosis” to each clinician; follow up with clinician to ensure completion of the tutorial.
  - iii. Panel radiologist – Ensure radiologist is licensed in country of operation. Ensure ongoing review and oversight.
- b. Refugee TB education
  - i. Keep general TB education course; continue efforts to find funding to enable the development of ongoing TB education using refugee community members as peer educators.

- ii. Keep sputum training video; ensure patients have opportunity to ask questions before being asked to produce sputum specimen.
- iii. Ensure coordinated, consistent TB education for all persons with positive smear, culture, or tuberculin skin test, fully utilizing the teachable moment when the patient is most motivated to learn.
- c. Refugee cultural orientation education
  - IOM should continue the ongoing evaluation of the Cultural Orientation (CO) course to ensure its added value for refugee participants; this should include revising and enhancing the CO course based on feedback from refugees who have already resettled in the United States.

## **Recommendations for DGMQ and DTBE**

- 1) Program indicators for monitoring and evaluating this refugee population have been developed (see Appendix 2). In this setting of high-volume screening, the indicators should be reported and analyzed monthly by DTBE and DGMQ and reviewed with IOM leadership.
- 2) There are dissimilarities between refugee and immigrant screening. The team feels that it has a good grasp of the challenges and issues associated with refugee screening, but not for immigrant screening. DGMQ should conduct an independent assessment of the key immigrant screening programs.
- 3) Opportunities for ongoing education are essential for panel radiologists and panel physicians. DGMQ and DTBE should specify the minimum amount of training required and, with Dept of State support, provide opportunities for such training to be obtained.
- 4) CDC should review training materials previously developed for panel physicians; consider revising and updating these training materials to be consistent with the 2007 new Technical Instructions. DGMQ and DTBE should also consider contracting for the development of a TB Intensive Course specific for Panel Physicians.
- 5) DGMQ, with regulatory authority to stipulate the requirements for overseas medical evaluation, and DTBE, the reservoir of technical expertise for tuberculosis must work together seamlessly in conducting and evaluating successful refugee and immigrant screening programs.
- 6) Establish a network of knowledgeable and interested clinical consultants to be available via e-mail for rapid consultation on difficult screening and treatment decisions that face panel physicians, including those that pertain to MDR TB or potential XDR-TB.
- 7) DGMQ should monitor the quality and equivalency of TST solutions being used for overseas screening.
- 8) DTBE should develop a surveillance system for detecting smear-positive TB cases that occur in refugees within 60 days after arrival to the U.S.
- 9) DTBE and DGMQ should work with IOM to analyze data and prepare a manuscript to describe the screening process and outcomes from Tham Hin and Mae La camps.

- 10) DGMQ should work to establish capacity in the U.S. to directly utilize IOM's computed radiography and electronic records in state and local programs that evaluate refugees.
- 11) The lab director (Mr. Warren Jones) is heavily involved in building laboratory capacity for DGMQ-supported screening programs throughout the region, diluting his time to supervise IOM Mae La laboratory operations. DGMQ should ensure that adequate onsite supervision is maintained during Mr. Jones' absences.
- 12) DGMQ should work with the Dept of State to review and correct the regulation that prevents refugees from entering OPE processing and booking with pending laboratory specimens.
- 13) Revise the form for recording radiograph findings, as it contains descriptions that are not consistent with TB-related findings.
- 14) DTBE should develop and implement a U.S.-based communication plan regarding resettlement of the Burmese refugees. (See Appendix 1 for draft communication plan with key needs and strategies identified.)

## **Recommendations for 2007 NEW TB Technical Instruction Revisions**

- 1) Incorporate TST into the evaluation of contacts; assign a TB classification to TST-positive contacts to ensure appropriate follow-up in the U.S. (IOM rec 9 b).
- 2) Review and revise the recommendation regarding not treating patients with extrapulmonary TB overseas to allow for treatment when the patient may worsen without it (IOM rec 5 b).
- 3) For this resettlement, continue pre-departure screening at three weeks prior to departure until further evaluation can be performed to determine the yield of this screening.
- 4) The team concurs with the decision to not routinely obtain CXRs in children under age 15, unless the child has a positive TST, is a family contact of a case or is symptomatic.
- 5) The definition of a contact is a person who has shared the same airspace in a household or other enclosed environment for a prolonged period (days or weeks, not minutes or hours) with a smear- and/or culture-positive pulmonary TB case.
- 6) For children under ten, recommend not requiring routine gastric aspirates during follow-up while on treatment for active TB.
- 7) The Technical Instructions, with regard to contacts, are ambiguous and need to be revised ( IOM rec 9 ).

# Appendices

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## Appendix 1

### **Key Education and Communication Strategies and Activities to Enhance the Resettlement Efforts of Burmese\* Refugees in the United States to Prevent, Treat, and Control Tuberculosis (TB)**

Develop and disseminate information to US-based health-care providers (with special emphasis on TB programs) and decision makers regarding resettlement of Burmese refugees. Include information on quality of TB refugee services received before arriving in the United States, as well as other health needs, cultural beliefs, and potential and available resources. Ensure messages are accurate, accessible, and do not create any unnecessary, negative reactions within communities or in the Burmese refugee population.

#### **Key Education and Communication Strategies and Activities**

- Develop mechanisms and materials to inform health-care providers in the public and private sectors about resettlement of Burmese refugees in the United States, quality of TB refugee services received before arriving in the United States, other health care needs, TB treatment prevention priorities and strategies, as well as related cultural beliefs and educational needs of this population;
- Develop mechanisms and materials to inform decision makers in the public and private sectors about resettlement of Burmese refugees in the United States and related TB prevention priorities and strategies.
- Coordinate and integrate TB prevention, diagnosis, and treatment information with health promotion strategies of other organizations with common interests in the resettlement of Burmese refugees;
- Provide and maintain mechanisms to facilitate regular, ongoing communication regarding resettlement of Burmese refugees regarding TB across federal agencies, and state and local program areas.

\*Burma (Myanmar) is the home country of the refugees. The refugees are Burmese, but not Burmans. The Burmans are the majority, ruling people of Burma. There are at least ten major ethnic groups and a hundred subtribes, with Burmans making up nearly two-thirds of the population. Others include the Shan (the largest minority), Karen, Karenni, Mon, Arakhan, Kachin, and Chin. Burmese is the official language, but non-Burmans speak their own tongue as the first language. English language skills are not common among the refugees.

## Strategies and Action Steps

Strategies	Action Steps
<p><b>1.</b> Develop mechanisms and materials to inform health care providers in the public and private sectors about Burmese refugee resettlement, including quality of TB refugee services received before arriving in the United States, other health care needs, TB treatment prevention priorities and strategies, as well as related cultural beliefs and educational needs of this population.</p>	<p>Review TB educational materials and communication products; update and revise to include messages relevant to Burmese refugee resettlement.</p> <p>Identify gaps in TB education and communication products regarding this population; develop new materials as needed.</p> <p>Inform providers about the IOM TB screening process for U.S.-bound Burmese refugees, including information on quality of TB treatment services.</p> <p>Inform providers serving Burmese refugees about prevention of TB, including the importance and benefits of detecting and treating LTBI, as well as appropriate detection and prompt reporting of TB cases.</p> <p>Provide information to health-care providers regarding cultural beliefs and educational needs of this population.</p> <p>Exhibit and present information at national medical, laboratory, and health educator meetings on resettlement of Burmese refugees, including TB diagnosis, treatment, and reporting.</p> <p>Inform health-care providers serving Burmese refugees of available TB training and medical consultation resources via the RTMCCs.</p>

Strategies	Action Steps
<p>2. Develop mechanisms and materials to inform decision makers in the public and private sectors about resettlement of Burmese refugees in the United States and related TB prevention priorities and strategies.</p>	<p>Collaborate with the National TB Controllers Association, Results, the National Coalition for Elimination of TB, and other organizations to develop an advocacy and communications strategic plan (including a media plan).</p> <p>Facilitate networking among TB programs and policymakers; activities can include the following:</p> <ul style="list-style-type: none"> <li>• Encourage TB controllers to communicate with legislators and community leaders, especially leaders from service organizations regarding resettlement and health needs of Burmese refugees.</li> <li>• Identify a communications contact person in each of the states or regions where Burmese refugees will be resettling.</li> <li>• Assist the TB programs to identify and utilize coordinated communication mechanisms within their state for disseminating information about this population (e.g., California TB Controller Association newsletter).</li> </ul> <p>Establish and maintain ongoing, systematic communication with policymakers. Material communicated to key policymakers can include recently released information on this population, relevant op-eds, and updates on program successes to keep them informed about the resettlement progress. Recommended activities include:</p> <ul style="list-style-type: none"> <li>• Create or enhance existing mechanisms to rapidly disseminate related information. The frequency and the method of communication must be tailored to the needs of each target audience segment.</li> <li>• Develop and disseminate messages to policy makers regarding Federal agency efforts and outcomes related to resettlement of this population, as well as the health needs.</li> <li>• Utilize members of the Advisory Council for the Elimination of Tuberculosis (ACET) to serve as spokespersons to assist in promoting the federal response to resettlement of Burmese refugees.</li> </ul>

<b>Strategies</b>	<b>Action Steps</b>
<p>3. Coordinate and integrate TB prevention, diagnosis, and treatment information with health promotion strategies of other organizations with common interest in the resettlement of Burmese refugees.</p>	<p>Collaborate with the National TB Controllers' Association, Results, and the National Coalition for Elimination of TB to develop an advocacy and communications strategic plan (including a media plan).</p> <p>Create a set of materials (e.g., a slide show presentation, informational fact sheets, and brochures) that can be used to inform community groups, managed care organizations, and provider groups about TB prevention and treatment in this population.</p> <p>Utilize the structures and communication vehicles of "influencers" of health care providers (e.g., managed care organizations, medical and nursing societies, local chapters of professional organizations) to disseminate information about TB treatment in this population.</p> <p>Collaborate with the National Tuberculosis Curriculum Consortium (NTCC) to include information on TB treatment in Burmese refugees in educational materials being developed for health care providers in training.</p>
<p>4. Provide and maintain mechanisms to facilitate regular, ongoing communication across federal agencies, and state and local program areas regarding resettlement of Burmese refugees regarding TB across federal agencies, and state and local program areas.</p>	<p>Develop TB updates and disseminate on an ongoing basis to federal staff, TB control programs, refugee programs, and other public health agencies involved with Burmese refugee resettlement; ensure U.S. public health programs are aware and have ready access to CDC information and educational materials.</p> <p>Develop a generic package of TB/Burmese refugee information including fact sheets, Frequently Asked Questions, Notes to the Press, and briefing notes that can be updated as required and disseminated to federal agencies, state and local TB programs, RTMCCs, and other interested organizations.</p> <p>Identify federal staff, NTCA members to serve as key spokespersons regarding resettlement of Burmese refugees; all NTCA members should ensure ongoing dissemination of TB/Burmese information.</p> <p>Develop and disseminate messages regarding Federal agency, state and local efforts and outcomes related to resettlement of Burmese refugees.</p>

## **Appendix 2**

### **Recommended Laboratory and Program Indicators**

Initially, the cohort period for analysis should be monthly. The cohort should include all refugees who initiate screening from the first of the month to the last of the month. In order to ensure that sufficient time is provided to finalize the data for analysis, a data closure date needs to be defined. For these indicators, the last date when the most current information can be entered and after which data analysis can be performed will be referred to as the data closure date. For an indicator that will be reported monthly, a data closure date of 2 weeks means that the previous month's dataset will be closed 2 weeks after the last day of the previous month. This time period will vary for the different indicators. Reporting frequency and data closure dates will have to be reviewed and revised as experience is gained with these indicators.

#### **1. Refugees initiating screening**

- a. Definition: Refugees initiating screening are those who have had at least a physical examination by a panel physician.
- b. Analytic cohort: refugees registered to undergo Health Assessment during cohort period.
- c. Data closure date: 2 weeks.

#### **2. Tuberculosis suspects**

- a. Definition: Tuberculosis suspects are those with chest radiographs suggestive of tuberculosis or those with symptoms suggestive of tuberculosis, either of which will lead to specimen collection for acid fast bacilli smear microscopy and culture. Tuberculosis suspects include those who may have extrapulmonary tuberculosis.
- b. Analytic cohort: cases initiating screening during cohort period
- c. Data closure date: 2 weeks.

#### **3. Final diagnosis of tuberculosis**

- a. Definition: Diagnoses can be based on culture, smear microscopy, or clinical criteria. Cases can be pulmonary (with or without extrapulmonary disease) or exclusively extrapulmonary.
- b. Analytic cohort: cases initiating screening during the cohort period
- c. Data closure date: 10 weeks.

#### **4. Initial drug susceptibility results**

- a. Definition: Possible drug susceptibility results include pansusceptible, INH monoresistance, rifampin monoresistance, MDR, XDR, and "other DST resistance" patterns.
- b. Analytic cohort: Except for XDR, the cohort will be cases that are culture positive and that had first-line DST performed. For XDR, the cohort will be cases of MDR that had second-line DST performed.
- c. Data closure date: 14 weeks

## **5. Results of therapy**

- a. Definitions: cases that completed therapy within 12 months, defaulted, failed, died during therapy, or who were still on therapy 12 months after beginning. Completion of therapy means that the patient received an appropriate regimen based on drug susceptibility test results delivered by DOT. In addition, patients who are cured will be defined as those who have two cultures that are negative; data on rates of cure will be reported separately for MDR TB cases and XDR TB cases.
- b. Analytic cohort: Cases that began therapy at least 12 months before data are finalized, since cases can take up to 12 months to receive a complete drug regimen and still be classified as having completed therapy.
- c. Data closure date: 12 months plus 2 weeks.

## Appendix 3 Key Staff

### Key IOM Staff Involved in TB Screening and Treatment for U.S-Bound Refugees

Name	Title	Responsibilities related to medical screening in Thailand
<b>Irena Vojáčková-Sollorano</b>	Chief of Mission and Regional Representative	Regional Representative
<b>Thomas O'Rourke, MD, MPH, DTM&amp;H</b>	Regional Medical Officer	Oversight of all medical operations for IOM in Thailand
<b>Warren Jones</b>	Regional Laboratory Manager	Oversight and leadership of IOM Medical Laboratories in the region; laboratory and staff development at pace with programmatic targets
<b>Dr. Rachain Weannara Dr. Somruetai Painual Dr. Raz M. Wali Dr. Melissa Sindiong Dr. Nguyen Ngoc Yen</b>	IOM Physicians	Medical screening, diagnosis and treatment for U.S.-bound refugees
<b>Rawee Arpornsilp Taanapat Prachavamethawe</b>	Lead Laboratory Technicians	Oversight of sputum collection, processing of laboratory specimens, interpreting culture and DST results, posting results, informing treating physicians of relevant findings
<b>Subin Nandalok</b>	Health educator	
<b>Sugunya Prayadsab Suwaluck Nilboran Vanida Ngamlertnapaporn Tanutkorn Sumanangkul Mathika Thongkhamkitcharoen</b>	IOM Head Nurse Nurse Nurse Nurse	Oversight and administration of DOTS program
<b>Sugunya Prayadsab</b>	IOM Head Nurse	Acquisition and storage of pharmaceuticals
<b>Dr. Phattawii</b>	Local hospital hire radiologist	
<b>Melissa Varma, MD</b>	Physician	Clinical management of Hmong with MDR tuberculosis, oversight of TB treatment of USRP refugees in Mae La
<b>Alison Quartaro</b>	CDC Projects Coordinator	Coordination and implementation of surveillance activities, epidemiological, financial and internal reporting; assistance with logistics and technical skills related to medical unit

**Key NGO Staff Involved in TB Screening and Treatment  
for US-Bound Refugees**

<b>Name</b>	<b>Title</b>	<b>Responsibilities</b>
<b>Anabelle Djeribi</b>	Country Director, Aide Médicale Internationale (AMI)	
<b>Jean-Louis Mosser</b>	Medical Director, Aide Médicale Internationale (AMI)	Oversight of all medical treatment at Mae La Camp with the exception of TB
<b>Dr. Daw Tin Shwe (Valerie)</b>	Epidemiologist, Aide Médicale Internationale (AMI)	Monitoring and reporting of disease statistics in Mae La, Umpien, and Nupoe Camps, outbreak investigation and response in coordination with MOPH, MOI and others
<b>Olivier Camelique</b>	Medical Coordinator, Médecins Sans Frontières (MSF)	
<b>Andres Romero</b>	Field Coordinator, Médecins Sans Frontières (MSF)	
<b>Janne Krause</b>	Medical Officer, Médecins Sans Frontières (MSF)	Treatment of TB patients in TB Village, Mae La Camp
<b>Cathy Hewison</b>	TB Medical Referent, Médecins Sans Frontières (MSF)	